EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

OPPOSITION TO MORTON GROVE PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S COUNTERCLAIM

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTRODUCTION

Morton Grove Pharmaceuticals, Inc. ("Morton Grove") bases its motion to dismiss on the erroneous premise that defendant the National Pediculosis Association, Inc. ("NPA") sued Morton Grove for political statements it made. This assertion conflicts with the well-pled allegations in NPA's counterclaim that Morton Grove's statements are part of a commercial advertising and promotional campaign. Morton Grove's motion violates the basic tenets of motions to dismiss: all well-pled allegations in the complaint must be taken as true and all reasonable inferences are to be made in favor of the non-movant. Applying these standards to the actual allegations in the counterclaim (as opposed to Morton Grove's characterization of them), NPA's counterclaim states claims under the Lanham Act and Illinois Deceptive Trade Practices Act. Accordingly, Morton Grove's motion to dismiss should be denied. Furthermore, Morton Grove's request for sanctions in the conclusion of its memorandum of law in the form of an "invitation" to the Court to consider imposing sanctions on its own initiative fails to comply with Federal Rule of Civil Procedure 11 and is completely unfounded; therefore, it should be rejected by the Court.

FACTUAL ALLEGATIONS

Morton Grove manufactures and sells two prescription lice and scabies pesticidal treatments containing the chemical lindane, Lindane Lotion USP 1% and Lindane Shampoo USP 1%. (NPA Counterclaim, hereinafter "CC", ¶ 1.) Over the last fifteen years, in light of the toxicity and dangers of pharmaceutical lindane, the U.S. Food and Drug Administration ("FDA") and other government entities have imposed increasingly stringent restrictions on the packaging, labeling and approved uses of Morton Grove's lindane products. (*Id.*) Today these products are banned in California and may be sold elsewhere in the United States only in single-use packages

containing an FDA-mandated "black box" warning that details some of the reported risks of their use. (*Id.*; *see also id.* ¶¶ 20-24.)

In response to these events, Morton Grove engaged in an aggressive, targeted promotional campaign designed to mislead both consumers and healthcare professionals about the dangers of its lindane products. (CC ¶ 2.) As part of this campaign, Morton Grove has advertised and promoted its lindane pesticidal treatments in a manner that disregards their risks and use restrictions, including those contained in the FDA's mandated "black box" public health warning concerning those products. (*Id.* ¶ 3.)

In particular, Morton Grove has targeted pediatricians and other healthcare professionals, seeking to convince them to write prescriptions for, or recommend use of, these products despite the increasing regulatory scrutiny of pharmaceutical lindane and despite the risks described in the FDA's black box warning and elsewhere. (CC ¶¶ 27-28.) For example, in May 2006, Morton Grove sent at least five form letters to pediatricians and other healthcare professionals which contained misleading impressions regarding the safety of Morton Grove's lindane products. (*Id.* ¶¶ 35-36, 46-59, 76-106.) Additionally, Morton Grove created websites, including lindane.com and lindanetruth.com, which similarly promoted its lindane products through misleading statements. (*Id.* ¶¶ 60-75.) Morton Grove continued to promote its lindane products by using misleading statements about their safety and efficacy despite a 2007 FDA Warning Letter to Morton Grove that chastised Morton Grove for downplaying the risks associated with its lindane products in previous promotional materials. (*Id.* ¶¶ 29-34, 60.)

Also as part of its marketing campaign, Morton Grove has sought to discredit NPA and other non-profit organizations that warn about the dangers of the chemical lindane and its use in lice and scabies treatments. (*Id.* ¶¶ 1, 110-118.) Among other things, Morton Grove has falsely

accused NPA of being a sham non-profit organization that speaks out about the dangers of lindane pesticidal treatments only as a pretense so that it can increase its profits through sales of its allegedly defective LiceMeister® comb. (*Id.* ¶¶ 111-118.)

NPA filed its counterclaim to redress the false and misleading statements made by Morton Grove regarding Morton Grove's lindane products and NPA's services and business. (*Id.* ¶ 5.) Although NPA's primary position is that it is not a competitor of Morton Grove's, NPA brought its counterclaim in case the Court determines that NPA and Morton Grove are competitors in connection with Morton Grove's claims. (*Id.* ¶ 7.)

ARGUMENT

It is well-settled that in evaluating Morton Grove's motion to dismiss, the Court must "accept all well-pled facts in [NPA's counterclaim] as true." *Balthazar v. Sw. Bell Corp.*, 494 F. Supp. 2d 930, 931 (N.D. Ill. 2007) (citations omitted) (denying motion to dismiss because of well-pled facts in complaint). It also must "view those allegations in the light most favorable to [NPA] and make all reasonable inferences in [its] favor." *Sanner v. Board of Trade*, 62 F.3d 918, 925 (7th Cir. 1995) (citation omitted). Furthermore, Morton Grove "cannot, in presenting its 12(b)(6) challenge, attempt to refute the complaint or to present a different set of allegations." *Id.* (quotation omitted) (affirming denial of motion to dismiss where motion was based on allegations contrary to complaint). In its "legal framework" section, Morton Grove does not even acknowledge these fundamental principles (MG Mem. at 6-7), but rather bases its motion on allegations and characterizations that directly contradict those in the counterclaim. As such, Morton Grove's motion to dismiss should be denied.

I. COUNT II STATES A CLAIM FOR FALSE ADVERTISING UNDER THE LANHAM ACT.

A. Count II Sufficiently Alleges That The Statements At Issue Are Commercial Advertisements Or Promotions.

1. The counterclaim alleges that Morton Grove's letters sent to pediatricians and other healthcare professionals are commercial advertisements because they enhance its competitive position.

Morton Grove argues that its letters to pediatricians and healthcare professionals cannot be commercial advertisements because they were targeted to specific individuals and do not propose a commercial transaction. (MG Mem. at 8-9.) Contrary to Morton Grove's claim, targeted advertising campaigns can be commercial advertisements under the Lanham Act. The dispositive issue is not whether the letters were personalized, but rather the purpose of the letters. If the letters could affect purchasing decisions, even indirectly, they are actionable.

For example, in *Republic Tobacco v. North Atlantic Trading Co.*, No. 98 C 4011, 1999 WL 261712 (N.D. Ill. Apr. 9, 1999) (App. 1)[1], a case cited by Morton Grove, the Court denied the defendant's motion to dismiss a Lanham Act false advertising claim that was based on a letter sent to one of the plaintiff's distributors, statements made to distributors who sold both parties' products and letters to sent to defendant's customers, many of whom also were the plaintiff's customers. *Id.* at *2-3, 8. The Court rejected the defendant's argument that these isolated communications made to "middlemen" could not be commercial advertisements because the defendant made multiple communications and the statements were made to the distributors "for the purpose of enhancing its competitive position, directly or indirectly, with the consuming public." *Id.* at *7-8. As the Court explained, "the Lanham Act does not require the allegedly false statements to reach the ultimate consumer before they are actionable." *Id.* at *8.

[1] Citations to "App." refer to the appendix of unpublished cases that accompanies this memorandum. Citations to "Ex." refer to exhibits attached to this memorandum.

The Court in *Health Care Compare Corp. v. United Payors & United Providers, Inc.*, No. 96 C 2518, 1998 WL 122900, at *3-4 (N.D. Ill. Mar. 13, 1998) (App. 2), reached a similar conclusion. In *Health Care*, the plaintiff claimed that statements the defendant, another healthcare network operator, made to healthcare providers (doctors and hospitals) violated the Lanham Act. *Id.* at *1-2. The defendant moved for summary judgment claiming that the statements could not be false advertisements because the true consumers are the employers and insurance companies who buy the network services. *Id.* at *3. The Court denied the motion, holding that "it is enough if the false advertising is directed to an identifiable group that the advertiser seeks to persuade for the purpose of enhancing its competitive position, directly or indirectly, with the consuming public." *Id.* at *4.

Indeed, "[s]peech need not closely resemble a typical advertisement to be commercial." *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 112 (6th Cir. 1995). In *Semco*, the plaintiff sued a competitor for statements made in a trade journal article. *Id.* at 110. The competitor successfully moved for summary judgment on the ground that the article was not a commercial advertisement within the meaning of the Lanham Act. *Id.* The Sixth Circuit reversed, holding that the "article does refer generally to [defendant's] products, and a rational jury could easily find that [defendant] had an economic motivation for submitting the article through its president" thus satisfying the commercial advertising prong. *Id.* at 112-13. "[T]he alleged misrepresentations contained in the [defendant's] article represent commercial speech and are actionable under the Lanham Act." *Id.* at 113-14; *see also Healthport Corp. v. Tanita Corp. of Am.*, No. 06-419-PK, 2008 WL 2224398, at *7 (D. Or. May 23, 2008) (App. 3) (holding that false statement concerning credentials of defendant's president actionable under Lanham Act

even though statement did not relate directly to product because it "may deceive consumers and influence consumer decisions on whether to purchase" defendant's product).

As in these cases, Morton Grove sent letters to pediatricians and other healthcare professionals in an attempt to sell more products, at least indirectly. In the letters, "Morton Grove seeks to convince them to write prescriptions for, or recommend use of, these products despite the increasing regulatory scrutiny of pharmaceutical lindane, and despite the risks described in the FDA's black warning and elsewhere." (CC ¶ 28; *see also* i*d.* ¶ 35.) Morton Grove also mentions its own products by name and tries to downplay the risks associated with them so that doctors will be more likely to prescribe these medications. (*Id.* ¶ 37 & Exs. B-F.) Because these products are available only with a prescription, doctors and other healthcare professionals are key to the purchasing decision even though they are not the ultimate consumers. Therefore, these letters are commercial speech. Morton Grove's argument that they cannot be commercial advertisements because they do not tell how "Lindane medications can be obtained" (MG Mem. at 9) is meritless because the letters were sent to doctors and others who know how to obtain prescription-only medicines without having to be told that information.

Furthermore, Morton Grove's reliance on *American Needle & Novelty v. Drew Pearson Marketing, Inc.*, 820 F. Supp 1072 (N.D. Ill. 1993), is misplaced. In *American Needle*, the plaintiff alleged that the defendant violated the Lanham Act by sending a letter to the National Basketball Association ("NBA") informing it that the defendant, an NBA licensee, had terminated its distribution agreement with the plaintiff. *Id.* at 1074-75. The defendant moved to dismiss on the ground that the letter "was not sent to the NBA for purposes of influencing consumers to purchase its licensed headwear." *Id.* at 1077. The Court agreed, explaining that even though "the Lanham Act does not require allegedly false statements to reach the consuming

public before they are actionable. . . a single letter privately addressed to a non-consuming licensor" was not sufficient. *Id.* at 1077-78.

Unlike in *American Needle*, Morton Grove did not send one isolated letter; there were at least five letters as well as statements on its public websites. Also, while the letters were addressed to individuals, they were not "individualized lobbying pitches" as Morton Grove suggests. Indeed, Morton Grove admits that they were form letters with identical content. (MG Mem. at 4; *see also* CC ¶¶ 46-59 & Exs. B-F.) And, importantly, the recipients of Morton Grove's letters, unlike the NBA, were involved in the ultimate purchasing decision because they have to write the prescriptions in order for consumers to buy Morton Grove's products.

2. The counterclaim adequately alleges that lindane.com is a promotional website.

Morton Grove argues that statements on lindane.com are not actionable because the website "is purely informational, exists exclusively for lobbying purposes, and is not a promotional website." (MG Mem. at 9.) As a preliminary matter, NPA sued for statements made on two different websites: lindane.com and lindanetruth.com. Morton Grove makes no arguments as to why the statements on lindanetruth.com are not actionable, and thus its motion to dismiss should be denied with respect to those statements.

With respect to the statements on lindane.com, Morton Grove's argument is meritless. First, Morton Grove's argument that lindane.com exists "exclusively for lobbying purposes" and was launched in "response to the misleading and unfounded information about" its products directly conflicts with the well-pled allegations in the counterclaim.[2] (MG Mem. at 9, 11.) The

[2] Morton Grove also argues that the website cannot be promotional because the members of the website's advisory panel "may not have offered to participate in a commercial website." (MG Mem. at 11.) Morton Grove cites no authority that this factor (if true) is relevant. Moreover, it is misleading because at least one member is Morton Grove's paid consultant, as NPA recently learned in a deposition. Morton Grove refuses to provide information regarding the other members.

counterclaim alleges that "in response to the increasing scrutiny of the chemical lindane and its pharmaceutical uses, Morton Grove launched an aggressive advertising and promotional campaign designed to minimize the dangers and risk of using [Morton Grove's products]." (CC ¶ 26; *see also id.* ¶ 60.) That campaign included "creation and maintenance of two websites, www.lindane.com and www.lindanetruth.com." (*Id.* ¶ 27; *see also id.* ¶ 61.) "These two websites are one component of Morton Grove's overall marketing and advertising strategy regarding its products. . . . These websites function an as important portal for non-personal selling" of those products. (*Id.* ¶ 62.) Because Morton Grove's argument impermissibly rejects the counterclaim's allegations, it should be denied. *See Sanner*, 62 F.3d at 925.

Second, Morton Grove's characterization of lindane.com directly conflicts with that of the marketing agency that Morton Grove hired to develop that website, Closerlook.[3] (Ex. 1.) Closerlook stated that lindane.com was aimed at consumers and doctors, not just legislators. (*Id.*) Closerlook's description is consistent with lindane.com itself, which can be accessed by anyone. There is nothing on lindane.com informing consumers and doctors that this is the wrong website for them or directing them to Morton Grove's purported commercial website. Also, lindane.com contains statements that are virtually the same as ones that appeared on lindane4lice.com, an undisputedly commercial website, before the FDA required Morton Grove to change that website. (CC ¶¶ 60, 76-106 & Ex. A.)

Third, Morton Grove's argument that it maintains a separate promotional website, mgp-online.com, should be disregarded because it relies on "facts" outside of the counterclaim and is

[3] The Court may consider this additional information even though it was not alleged in the counterclaim. *See Balthazar*, 494 F. Supp. 2d at 931-32 (denying motion to dismiss in part based upon affidavit submitted in opposition to motion, stating that "plaintiff may add essential facts 'by affidavit or brief in order to defeat a motion to dismiss if the facts are consistent with the allegations of the complaint'") (citation and quotation omitted).

belied by the actual content of that website. (MG Mem. at 5.) In addition, a review of mgp-online.com demonstrates that it does not even meet the criteria that Morton Grove claims are necessary for a promotional website. While there is a listing of Morton Grove products, consumers cannot purchase these products on the website, nor are there links to any commercial websites where such a purchase can be made. (Ex. 2.) Moreover, mgp-online.com does not include a statement concerning the side effects or warnings for these products even though such information must be included in any promotion of them, but that information is posted on lindane.com. (Ex. 3 at 3-43, 47-48.)

Fourth, as explained above (pp. 5-6), statements need not be traditional advertisements to be actionable under the Lanham Act. Lindane.com contains numerous references to Morton Grove's lindane products. (Ex. 3 at 1-42, 45-53.) There is even a section on how Morton Grove has made "advancements" to these products. (*Id.* at 43-53.) As such, lindane.com is a commercial advertisement within the meaning of the Lanham Act. *See Semco*, 52 F.3d at 112.

Fifth, the cases cited by Morton Grove are inapposite. (MG Mem. at 10.) None concern the false advertising section of the Lanham Act. Instead they involve trademark dilution or infringement claims brought against disgruntled customers or other cyber-gripers who set up websites to complain about the plaintiff.[4] Accordingly, the plaintiffs in those cases could not establish liability on the basis that defendants could benefit directly or indirectly from increased sales as a result of statements on their website. As one court explained: "Any harm to [plaintiff] arises not from a competitor's sale of a similar product under [plaintiff's] mark, but from

[4] *See Bosley Med. Inst., Inc. v. Kremer*, 403 F.3d 672, 674-75 (9th Cir. 2005) (dissatisfied customer); *TMI, Inc. v. Maxwell*, 368 F.3d 433, 438 (5th Cir. 2004) (disgruntled customer); *Taubman Co. v. Webfeats*, 319 F.3d 770, 772-78 (6th Cir. 2003) ("fan" and then cyber-griper); *Utah Lighthouse Ministry, Inc. v. Discovery Computing, Inc.*, 506 F. Supp. 2d 889, 898 (D. Utah 2007) (parody of website critical of church).

[defendant's] criticism of their services." *Bosley*, 403 F.3d at 680. In contrast, as explained above, the counterclaim alleges that Morton Grove used lindane.com to increase sales of its lindane products (or at least minimize a drop in sales) by downplaying the risks of its products to doctors and consumers. Also, none of Morton Grove's cases involve a motion to dismiss; instead, in each case, the court found that the website was not commercial only after an evidentiary hearing, not on a motion to dismiss where the complaint alleged otherwise.[5]

Similarly, *Midwest Canvas Corp. v. Commonwealth Canvas, Inc.*, No. 07 C 0085, 2008 WL 162757 (N.D. Ill. Jan. 16, 2008) (App. 4), is readily distinguishable. In *Midwest*, the plaintiff sued the defendant for a statement on the website of the New York Department of Transportation ("NYDOT"). *Id.* at *1-2. The Court held that the statement could not be a commercial advertisement because the NYDOT, "a state governmental entity, is not in direct commercial competition with any of the companies whose [products] are listed on the website, including [plaintiff and defendant]." *Id.* at *4. The Court also noted that the NYDOT statement was not an inducement to buy any product, but instead was part of quality assurance program that listed approved products. *Id.* at *5. Unlike in *Midwest Canvas*, Morton Grove is not a governmental entity, but rather it claims to be NPA's direct competitor. As explained above, Morton Grove designed lindane.com for consumers and doctors, not just for "lobbying" purposes. Also, providing "information" by way of downplaying the products' risks to consumers or to doctors who may prescribe the products is for one purpose and one purpose only -- to get them to ask for or prescribe these products.

[5] *See Bosley*, 403 F.3d at 675 (summary judgment); *TMI*, 368 F.3d at 434 (bench trial); *Taubman*, 319 F.3d at 774 (preliminary injunction); *Utah Lighthouse*, 506 F. Supp. 2d at 894 (summary judgment).

3. The counterclaim alleges that the testimonials on lindane.com are commercial advertisements.

Morton Grove argues that the testimonials of Drs. Shwayder and Hebert are not actionable because they were sent to legislators. (MG Mem. at 11-12.) While that may have been the original purpose, Morton Grove subsequently posted these letters on its commercial website, lindane.com. Morton Grove posted these letters, which downplay the risks of Morton Grove's lindane products, for economic gain. Thus, they are commercial advertisements. (*See* pp. 4-10, above.)

Furthermore, contrary to Morton Grove's argument (MG Mem. at 16), a party can be liable for statements made in third-party testimonials. In *Criticare Systems, Inc. v. Nellcor Inc.*, 856 F. Supp. 495, 498-99 (E.D. Wisc. 1994), the plaintiff sued for false advertising under the Lanham Act based on a letter from a third-party doctor to another doctor that the defendant showed to a potential customer. The court denied defendant's motion for summary judgment because the defendant could be liable for using that third-party letter. *Id.* at 507; *see also Patient Transfer Sys., Inc. v. Patient Handling Solutions, Inc.*, No. CIV.A. 97-1568, 2001 WL 936641, at *18 (E.D. Pa. Aug. 16, 2001) (App. 5) (holding defendants liable for false advertising under the Lanham Act based on statements in testimonial letters).

Indeed, if Morton Grove's argument were correct, the Court should dismiss Morton Grove's claims against NPA based upon NPA's posting on its website a third-party document, entitled "Statement in Support of the Elimination of Lindane Use in North America," which was sent to North American governmental entities asking them to ban lindane. (*See* Dkt. No. 1, Compl. at Ex. A.)

B. Count II Sufficiently Alleges That It Is Based On Morton Grove's Commercial Speech.

1. The Lanham Act's narrow political speech exception is inapplicable because the statements concern Morton Grove's products.

Morton Grove's attempt to shoe-horn its statements into the protected political speech exemption to the Lanham Act is unavailing. First, Morton Grove again impermissibly contradicts the well-pled allegations of the counterclaim and the actual content of lindane.com. Lindane.com does not have the indicia of a "political" website. Access to the website it not limited to states where legislation is pending or just to legislators or other government officials, but instead is accessible to anyone surfing the Internet. Also, it does not encourage its audience to take any political action, such as writing letters to legislators.

Second, it is well established that if speech concerns the speaker's product and is made for the speaker's economic gain, it is commercial speech. In the seminal case, *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), a contraception manufacturer argued that informational pamphlets it distributed about venereal disease were not commercial speech because they provided information about a matter of public interest. *Id.* at 62. The Court rejected Bolger's arguments because the pamphlets mentioned its products by name (even though one pamphlet only mentioned that Bolger was the distributor of certain condoms at the very end of booklet) and Bolger had an economic interest in sending them out. *Id.* at 62 n.4, 67-69. As such, the Court held that the pamphlets were commercial speech. *Id.* at 68. The reasoning in *Bolger* has been applied to Lanham Act false advertising cases. *See, e.g., Semco*, 52 F.3d at 112; *H & R Indus., Inc. v. Kirschner*, 899 F. Supp. 995, 1006 (E.D.N.Y. 1995).

Under the *Bolger* standard, even if the Court were to conclude that Morton Grove's website and letters provided information about safe and effective pesticidal treatments for lice and scabies, the statements still are actionable under the Lanham Act because, as explained

above, Morton Grove had an economic interest in making those statements, and it referred to its own products.[6] (*See* CC ¶¶ 26-28, 47-49, 53-59, 60-75.) Indeed, Morton Grove's references are far more substantial than those in *Bolger*. *See* 463 U.S. at 62 & n.4, 66 & n.12-13.

Third, Morton Grove's argument is premised on a partial quotation from the Lanham Act's legislative history. (MG Mem. at 12.) A look at the entire quote makes clear that the political speech exception is narrowly tailored and specifically excludes statements about goods and services. After the section quoted by Morton Grove, the legislative history continues: "'[h]owever, if a political or other similar organization engages in business conduct incidental to its political functions, then the business conduct would be considered 'commercial' and would fall within the confines of [§ 1125(a)].'" 134 Cong. Rec. H10,411-02 (daily ed. Oct. 19, 1988) (remarks of Rep. Katenmeier), *quoted in Am. Family Life Ins. Co. v. Hagan*, 266 F. Supp. 2d 682, 698 n.18 (N.D. Ohio 2002). As explained in *American Family*, "the 1988 presidential campaign was in full swing and the candidates were exchanging strident charges of misrepresentation. The addition of the word 'commercial' was meant to protect political candidates from civil liability under [§ 1125(a)]." 266 F. Supp. 2d at 698 n.18 (quotation omitted).

Furthermore, the Senate's legislative history shows that:

> "[T]he word 'commercial' is intended only to eliminate any possibility that the section might be applied to political speech. Although the Senate sees this language as unnecessary because section 43(a) requires that the misrepresentations be made with respect to good or services, we consider inclusion of the language so long as Congress' intent that it be interpreted only as excluding political speech is clear. It is also Congress' intent that the 'commercial' language be applicable any time there is a misrepresentation relating to goods or service."

[6] However, if the Court holds that Morton Grove's statements are not actionable because they involve this public debate, it also should dismiss Morton Grove's complaint against NPA because, as Morton Grove asserts (MG Mem. at 1), NPA was engaged in that same debate.

134 Cong. Rec. S16971 (daily ed. Oct. 20, 1988) (remarks of Sen. DeConcini), *quoted in Semco*, 52 F.3d at 111-12. In light of this legislative history and contrary to Morton Grove's claim (MG Mem. at 12), "the Lanham Act has been successfully invoked by and against parties engaged primarily in dissemination of political messages." *Am. Family*, 266 F. Supp. 2d at 694.

Fourth, the cases cited by Morton Grove are inapposite. *MasterCard International, Inc. v. Nader 2000 Primary Committee, Inc.*, No. 00 Civ. 6068, 2004 WL 434404, at *1 (S.D.N.Y. Mar. 8, 2004) (App. 6), involves Ralph Nader's use of MasterCard's "Priceless" trademarked slogan in his ads during his campaign for president. This is the quintessential political speech contemplated by the political exception inserted by Congress. Morton Grove's statements, on the other hand, were not made in the context of a campaign for public office. Similarly, in *Huntingdon Life Sciences, Inc. v. Rokke*, 978 F. Supp. 662, 666 (E.D. Va. 1997), PETA distributed a video and a press release concerning the plaintiff's animal testing practices. The court held that these items were not commercial speech because "[n]one of the allegations . . . specify an economic motive for PETA's actions."[7] *Id.* By contrast, here, the counterclaim is replete with allegations concerning Morton Grove's economic motives for the false statements it made. (CC ¶¶ 26-28, 47-49, 53-75.)

Finally, if Morton Grove's argument were correct about the political speech exemption, the Court should dismiss Morton Grove's claims against NPA that are premised on a third-party's statement sent to North American governmental agencies to ban lindane because that letter would be protected as part of the right to petition government.

[7] The court further noted that the plaintiff could not establish the video and press release were advertisements because PETA did not provide testing services, and thus PETA and the defendant were not direct competitors. *Id.* at 666-67.

2. Neither Noerr-Pennington nor a legislative privilege is applicable because Morton Grove did not make the statements to governmental entities.

Contrary to Morton Grove's claim (MG Mem. at 14-15), the *Noerr-Pennington* doctrine is inapplicable. In the cases cited by Morton Grove, the courts held that statements made to governmental agencies were not actionable. That is not the case here. NPA sued over statements Morton Grove made to doctors, medical organizations and on its public website. The case cited by Morton Grove, *Kottle v. Northwest Kidney Centers*, 146 F.3d 1056, 1059 n.3 (9th Cir. 1998), specifically states that "the Noerr-Pennington doctrine does not protect lobbying efforts directed at private organizations."[8] Similarly, the Seventh Circuit has held that: "The *Noerr-Pennington* doctrine is concerned solely with the right to attempt to influence government action. It thus immunizes only those actions directed toward governmental agencies or officials. The fact that a [party's action] may eventually provoke agency action or review does not alone call the *Noerr-Pennington* doctrine into play." *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1159-60 (7th Cir. 1983); *cf. Cardtoons v. Major League Baseball Players Ass'n*, 208 F.3d 885, 892 (10th Cir. 2000) (holding *Noerr-Pennington* inapplicable because a "letter from one private party to another private party simply does not implicate the right to petition").

Morton Grove's claim that a legislative privilege applies is equally flawed. (MG Mem. at 15-16.) As the cases Morton Grove cites make clear, that privilege applies to statements made to legislative bodies. (*Id.*) Again, Morton Grove has not been sued for making any such statements.

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[8] Moreover, *Eazypower Corp. v. Alden Corp.*, No. 03 C 3164, 2003 WL 22859492 (N.D. Ill. Dec. 2, 2003) (App. 7), is inapposite. In *Eazypower*, the Court explained that *Noerr-Pennington* has been applied to protect patent holders who send cease and desist letters to infringers because the patent laws require such letters; therefore, the letters were reasonably related to the petitioning litigation process. *Id.* at *2-3 This is not a patent case, and no law required Morton Grove to make the statements at issue before it could sue or otherwise petition the government.

C. Morton Grove's Statements Are Factual Assertions, Not Opinion.

Morton Grove argues that certain statements by Drs. Shwayder and Hebert are protected opinion. (MG Mem. at 17-18.) NPA agrees that there is a vigorous, contested debate about the safety and efficacy of lice treatments and that courts should be not be the arbiter of that debate. Accordingly, if the Court finds *McDonagh v. Bergan*, No. 03 C 1465, 2003 WL 21798735, at *3 (N.D. Ill. July 25, 2003) (App. 8), applicable to this case, the Court should dismiss Morton Grove's claims against NPA.

The statements by Drs. Shwayder and Hebert, however, do not implicate these concerns. As detailed in the counterclaim, the issue is whether Morton Grove violated the Lanham Act by posting on its websites: (1) Dr. Shwayder's letter which implies that Morton Grove's lindane products are safe to be used on pregnant women despite the FDA's labeling guidelines that these products should be used on pregnant women only if clearly needed and that there have not been adequate studies of the safety of this product on pregnant women; and (2) Dr. Hebert's letter which implies that Morton Grove's lindane products generally are safe to use on small children despite the black box warning that these products should be used with caution on children weighing less than 110 pounds. (CC ¶¶ 67-75.) It is difficult to see what constitutionally protected opinion is involved.[9] Indeed, courts routinely decide these types of issues in connection with Lanham Act claims. *See, e.g.*, *Criticare*, 856 F. Supp. at 506-07 (holding that defendant could be liable for false advertising for showing to a potential customer a letter from

[9] Moreover, Morton Grove's argument is based upon outdated case law. The Supreme Court in *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 17-19 (1990), rejected the old fact/opinion dichotomy in *Gertz v. Robert Welch, Inc.* 418 U.S. 323, 339-40 (1974). Instead, a statement can be actionable unless it "cannot 'reasonably [be] interpreted as stating actual facts.'" *Milkovich*, 497 U.S. at 20 (quotation omitted). This is the standard applied by the *McDonagh* court. 2003 WL 1798735, at *2.

one doctor to another doctor about the efficacy of plaintiff's medical product in connection with a specific case).

Furthermore, Morton Grove's claims that NPA sued over these statements to chill the doctors' free speech is without merit. (MG Mem. at 18-19.) NPA did not sue the doctors; it sued Morton Grove for posting those letters on its commercial website -- which it did for its own economic benefit. And, thus, it is Morton Grove that involved the doctors in this dispute.

D. Count II Sufficiently Alleges Causation.

Morton Grove's argument that "NPA has failed to properly plead causation" is incorrect. (MG Mem. at 21.) A plaintiff must allege that it "has been or is likely to be injured as a result of the false statement, either by a direct diversion of sales from itself to defendant or by a loss of goodwill associated with its product." *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999). The counterclaim sufficiently pleads this element: Morton Grove's false and misleading statements have injured NPA's goodwill in two ways: (1) "[b]y promoting [its products] through false or misleading statements . . . Morton Grove unfairly discredits NPA and hinders its efforts to educate the public about the dangers of lindane pesticidal treatments. Thus, as a result of these Morton Grove statements, NPA's 25-year reputation for educating the public after safe and effective options for managing and treating headlice has been irreparably tarnished" (CC ¶ 120); and (2) "to the extent that this Court determines that Morton Grove and NPA are competitors, Morton Grove's false and misleading advertising . . . negatively affects NPA's LiceMeister® Comb by increasing the market share of [Morton Grove's products] at the expense of market share of the LiceMeister® Comb" (*id.* ¶ 123).

Morton Grove argues that NPA has not satisfied *Hot Wax* because it cannot show how Dr. Shwayder's statements hurt NPA because he did not mention NPA and some of the statements concern his background. (MG Mem. at 21-22.) As Morton Grove concedes (MG

Mem. at 8), statements can be actionable under the Lanham Act if they concern either the defendant's or plaintiff's products. Furthermore, assuming that Morton Grove and NPA are competitors (as Morton Grove alleges), misleading statements that downplay the risks of Morton Grove's products could result in increased sales at the expense of NPA's sales. Also, to the extent that the false statements reject the positions that NPA has taken as part of its educational mission to be a public interest provider of information concerning lice treatments, NPA's services and goodwill in that regard may be injured.

Similarly, NPA does not allege that it was injured by statements about Dr. Shwayder's background. As explained in section I.C. above, the counterclaim alleges that the misleading aspect of Morton Grove's use of Dr. Shwayder's letter is that it suggests Morton Grove's products are safe to be used on pregnant women despite the FDA's labeling guidelines concerning such use. (CC ¶¶ 67-71.) Dr. Shwayder's qualifications are included only to give context to the misleading statement and because Morton Grove clearly believes (and a potential consumer might think) that Dr. Shwayder's credentials give credibility to the misleading statements. (MG Mem. at 18 (he is one of "the nation's most highly decorated and scholarly pediatric dermatologists").)

Furthermore, Morton Grove's reliance on *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986), is misplaced. *Matsushita* is an antitrust case, not a Lanham Act case, and the issue was "the standard district courts must apply when deciding whether to grant summary judgment in an antitrust conspiracy case." *Id.* at 576. In so doing, the Court held that "[i]t follows from these settled [summary judgment] principles that if the factual context renders respondents' claim implausible -- if the claim is one that simply makes no economic sense -- respondents must come forward with more persuasive evidence to support their

claim[s] . . . ." *Id.* at 587. This, however, is a motion to dismiss where the standards and burdens are significantly different. Moreover, NPA's counterclaim makes economic sense -- to the extent that NPA and Morton Grove are competitors, Morton Grove's misleading or false statements downplaying the risks of its own products hurt NPA.

II. COUNT I STATES A CLAIM UNDER THE ILLINOIS DECEPTIVE TRADE PRACTICES ACT FOR THE SAME REASONS THAT COUNT II STATES A CLAIM UNDER THE LANHAM ACT.

The parties agree that NPA's Illinois Deceptive Trade Practices Act claim ("IDTPA") should be analyzed under the same rubric as its Lanham Act claim. (MG Mem. at 19.) Because Count II states a claim under the Lanham Act, Count I, which is premised on the same factual assertions, states a claim under the IDTPA. Morton Grove then curiously argues that the IDTPA is more limited than the Lanham Act. Morton Grove argues that certain statements are not actionable because they are not about Morton Grove's goods and services, but instead are about personal experiences of certain doctors. (MG Mem. at 20.) As explained above, NPA is suing only on the portion of those statements that relate to Morton Grove's products.

Morton Grove also argues that two of the statements are not actionable because they do not mention Morton Grove's products. (MG Mem. at 20.) However, to be actionable, the statements do not have to refer to Morton Grove's products; they can refer to NPA's business or products. *See, e.g., M&R Printing Equip., Inc. v. Anatol Equip. Mfg. Co.*, 321 F. Supp. 2d 949, 952 (N.D. Ill. 2004). Furthermore, the statement in Paragraph 111 specifically refers to Morton Grove's own product. Moreover, to the extent that Morton Grove is arguing that the statements are not actionable because they disparage NPA's business as opposed to NPA's products, this argument is belied by the plain language of the IDTPA which includes disparagement of "goods, services or business of another by false or misleading misrepresentations of fact." 815 ILCS 510/2(8) (2008).

These terms have been broadly interpreted. In *Flentye v. Kathrein*, 485 F. Supp. 2d 903, 918-19 (N.D. Ill. 2007), the plaintiff sued under the IDTPA because on their website, the defendants falsely accused one plaintiff, "who is in the real estate business, of using a close circuit video camera for illegal and/or sexually motivated purposes and recording private activities through tenants' windows at night." The Court denied the defendants' motion to dismiss, holding that the plaintiffs had sufficiently stated a cause of action. *Id.* at 919. Applying this standard, Morton Grove's statements -- accusing NPA of making false statements about the efficacy of Morton Grove's product because NPA stands to profit from selling its comb -- disparage NPA's business and products.

Finally, Morton Grove argues that the statements concerning its own products do not disparage NPA's products. Not only is this inconsistent with Morton Grove's first argument that the statements need to mention its product, but it also is inconsistent with the law. A party can disparage another's product by making misleading statements about its own product. *See Native Am. Arts, Inc. v. Chico Arts, Inc.*, 8 F. Supp. 2d 1066, 1069 (N.D. Ill. 1998) (denying motion to dismiss IDTPA claim based upon misleading statement about own product).

III. MORTON GROVE'S SUGGESTION IN ITS CONCLUSION THAT THE COURT CONSIDER SANCTIONS UNDER RULE 11 IS IMPROPER AND WITHOUT MERIT.

In its conclusion, Morton Grove suggests that "[t]he Court should further consider Rule 11(c)(3) and order the NPA and its counsel to show cause why its conduct has not violated Rule 11(b)." (MG Mem. at 23.) Morton Grove's request is improper because it fails to comply with Federal Rule of Civil Procedure 11, which requires: "(1) that a request for sanctions be made in a separate motion rather than as an appendage to another motion or responsive memorandum, and (2) that the party to be sanctioned be given a twenty-one day safe harbor in which to withdraw or correct the allegedly offending filing." *Corley v. Rosewood Care Ctr., Inc. of*

Peoria, 142 F.3d 1041, 1058 (7th Cir. 1998) (citing Fed. R. Civ. P. 11(c)(1)(A)). Morton Grove did neither. For this reason alone, Morton Grove's request should be denied. *See, e.g.*, *id.* at 1058-59 (vacating award of sanctions, holding that district court abused its discretion because defendants failed to comply with Rule 11's procedural requirements); *Johnson v. Waddell & Reed, Inc.*, 74 F.3d 147, 151 (7th Cir. 1996) (vacating sanctions award based upon request in motion to dismiss because "the inclusion of a request for sanctions as part of [the party's] memorandum in support of its motion to dismiss obviously does not meet the notice requirement imposed by Rule 11(c)(1)(A)"). Morton Grove's attempt to circumvent these procedural requirements by inviting the Court to proceed under Rule 11(c)(3) should be rejected. However "packaged," Morton Grove's invitation is plainly a request for sanctions governed by the procedural requirements of Rule 11.

Moreover, while Morton Grove does not specifically identify the basis for its sanctions request -- an independent ground for denying sanctions[10] -- it appears to be based on Morton Grove's belief that it should prevail on its motion to dismiss. Assuming that this is the case, it is not a valid basis for sanctions. Instead, a "[p]otential violation of Rule 11 is analyzed under a negligence standard and turns on whether the conduct was objectively reasonable." *Papa John's Int'l, Inc. v. Rezko*, No. 04 C 3131, 2006 WL 566468, at *2 (N.D. Ill. Mar. 3, 2006) (denying motion for sanctions) (App. 9). Furthermore, a "sanction will not be imposed unless a specific allegation is utterly devoid of support." *Harding Univ. v. Consulting Servs. Group*, 48 F. Supp. 2d 765, 769 (N. D. Ill. 1999) (denying motion for sanctions).

10 S*ee Nagel v. ADM Investor Servs., Inc.*, 65 F. Supp. 2d 740, 756 (N.D. Ill. 1999) (failure to cited alleged Rule 11 violations with specificity waived movant's claim for sanctions), *aff'd*, 217 F.3d 436 (7th Cir. 2000).

Morton Grove has not come close to meeting this standard. As explained in detail above, Morton Grove's argument mischaracterizes the allegations in NPA's counterclaim, and NPA's claims under the Lanham Act and the IDTPA concerning Morton Grove's statements to doctors, medical organizations and on its websites are well supported by existing case law. Therefore, Morton Grove's request for sanctions should be denied. *See, e.g., Hartmarx Corp. v. Abboud*, 326 F.2d 862, 868 (7th Cir. 2003) (reversing sanctions award, holding that as long as party took "a reasonable legal position on the meaning" of the law, "it should not be sanctioned even if the district court concluded that [the other party] had the better reading").

CONCLUSION

As demonstrated above, Morton Grove's motion to dismiss is premised on factual assertions that are directly contrary to the well-pleaded allegations of the counterclaim. Applying the proper standards for a motion to dismiss, it is clear that NPA's counterclaim states claims under both the Lanham Act and the Illinois Deceptive Trade Practices Act. Thus, Morton Grove's motion to dismiss should be denied.

Dated: July 24, 2008

Respectfully Submitted,

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

By: s/ Debbie L. Berman
One of Its Attorneys

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CERTIFICATE OF SERVICE

I, Debbie L. Berman, hereby certify that on July 24, 2008, I caused copies of the foregoing **Opposition to Morton Grove Pharmaceuticals, Inc.'s Motion to Dismiss the National Pediculosis Association, Inc.'s Counterclaim,** to be served upon the following via electronic filing through the CM/ECF system:

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s/ Debbie L. Berman

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

OPPOSITION TO MORTON GROVE PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S COUNTERCLAIM

INDEX OF EXHIBITS

Exhibit 1	Excerpt from Closerlook website
Exhibit 2	Excerpts from mgp-online.com (now wockhardtusa.com)
Exhibit 3	Excerpts from lindane.com

EXHIBIT 1

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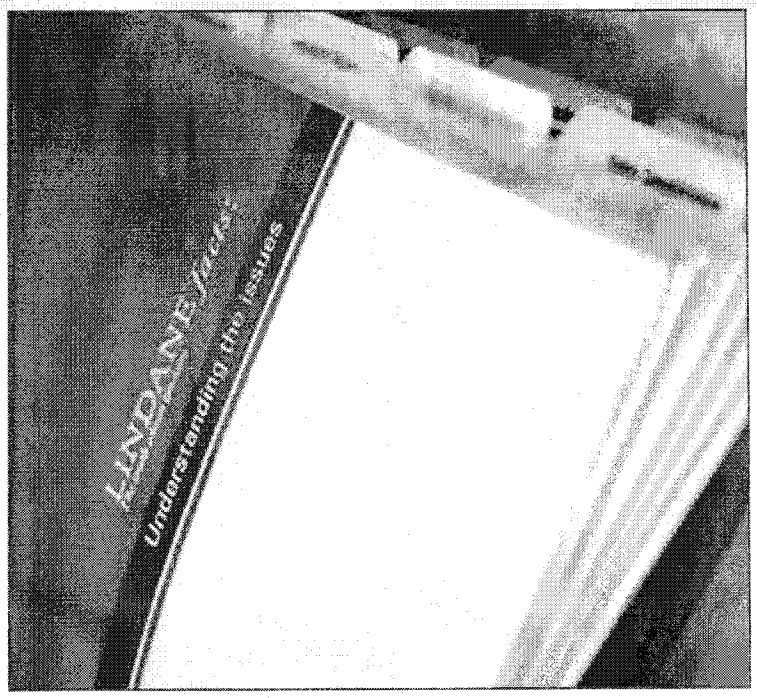
Morton Grove Pharmaceuticals

Morton Grove Pharmaceuticals, Inc., is a specialty pharmaceutical company that develops, manufactures and markets prescription oral liquid and topical liquid pharmaceuticals. The company manufactures and markets over 50 products. Morton Grove Pharmaceuticals is a leading manufacturer and marketer of prescription oral liquid pharmaceuticals in the United States.

Morton Grove Pharmaceuticals was faced with the urgent task of addressing a misleading communications movement that was negatively impacting its business. Inaccurate and distorted information had affected MGP's bottom line sales of lindane, and had resulted in the banning of lindane-based drug therapies in the state of California. MGP partnered with closerlook to launch "The truth about lindane" integrated communications campaign, to prevent further bans in other states and avert additional losses of yearly sales for MGP's lice and scabies second-line drug therapies. The overarching goal of the communication campaign was to set the record straight on the safety and efficacy of lindane prescription therapies - as defined by the FDA - to various audiences. closerlook created printed materials for direct communication between lobbyists and legislators as well as communication between lindane representatives and healthcare professionals (HCPs). A website was produced that spoke to a broader audience of legislators, HCPs, consumers, school nurses, and the media.

print
web



1 2 3 4

closerlook, inc.
212 West Superior Street / Suite 300 / Chicago, Illinois 60610
312.640.3700 main / 312.640.3750 fax / www.closerlook.com

EXHIBIT 2

WOCKHARDT USA

WOCKHARDT | MORTON GROVE

Wockhardt USA and Morton Grove Pharmaceuticals offer a generic and branded portfolio of over 50 products in a variety of dosage forms, including oral solids, liquids, topicals and injectables. Most products are manufactured in one of Wockhardt's global facilities and all are FDA-approved. To learn more about the FDA approval process, see our Knowledge Center.

Click Here for a detailed product listing. (PDF)

Wockhardt Name	Compares To	Therapeutic Category	Product Line
Acetaminophen & Codeine Phosphate Oral Solution	Tylenol w/Codeine®	Analgesic	Morton Grove
Acetic Acid Otic Solution	VoSol®	Anti-infective	Morton Grove
Amantadine HCl Syrup	Symmetrel®	Antiviral	Morton Grove
Amlodipine Besylate Tablets	Norvasc®	Calcium Channel Blocker	Wockhardt USA
Azithromycin Tablets	Zithromax®	Antibacterial	Wockhardt USA
Bethanechol Chloride Tablets	Urecholine®	Cholinergic Agent	Wockhardt USA
Captopril Tablets	Capoten®	ACE Inhibitor	Wockhardt USA
Carbamazepine Suspension	Tegretol®	Anticonvulsant	Morton Grove
Cefotaxime for Injection	Claforan®	Antibacterial	Wockhardt USA
Cefprozil Tablets	Cefzil®	Antibacterial	Wockhardt USA
Ceftriaxone for Injection	Rocephin®	Antibacterial	Wockhardt USA
Cefuroxime Axetil Tablets	Ceftin®	Antibacterial	Wockhardt USA
Cimetidine HCl Oral Solution	Tagamet®	Histamine H2-Receptor Antagonist	Morton Grove
Clarithromycin Tablets	Biaxin®	Antibacterial	Wockhardt USA
Clobetasol Propionate Topical Solution	Temovate®	Corticosteroid	Morton Grove
Cyclosporine Oral Solution	Sandimmune®	Immunosuppressant Agent	Morton Grove
Dexamethasone Elixir	Decadron®	Corticosteroid	Morton Grove
Dexchlorpheniramine Maleate Oral Solution	Polaramine®	Antihistamine	Morton Grove
Doxepin HCl Oral Solution	Sinequan®	Antidepressant	Morton Grove
Enalapril Maleate Tablets	Vasotec®	ACE Inhibitor	Wockhardt USA
Erythromycin Topical Solution	Eryderm®	Antibiotic	Morton Grove
Famotidine Tablets	Pepcid®	Histamine H2-Receptor Antagonist	Wockhardt USA
Fluoxetine Oral Solution	Prozac®	Antidepressant	Morton Grove
Fosphenytoin Sodium Injection	Cerebyx®	Anticonvulsant	Wockhardt USA
Furosemide Oral Solution	Lasix®	Diuretic	Morton Grove
Generlac Solution	Cephulac®	GI Agent	Morton Grove
Granisetron HCl Injection	Kytril®	Antinauseant/Antiemetic	Wockhardt USA
Hydrocodone and Homatropine Syrup	Hycodan®	Antitussive	Morton Grove
Hydroxyzine HCl Syrup	Atarax®	Antianxiety Agent	Morton Grove
Ketorolac Tromethamine Injection	Toradol®	NSAID	Wockhardt USA
Lactulose Solution	Chronulac®	GI Agent	Morton Grove
Lidocaine HCl Oral Solution	Xylocaine®	Anesthetic	Morton Grove
Lidocaine HCl Topical Solution	Xylocaine®	Anesthetic	Morton Grove
Lindane Shampoo	Kwell®	Antiparasitic	Morton Grove
Lisinopril Tablets	Zestril®	ACE Inhibitor	Wockhardt USA
Lithium Citrate Syrup	Cibalith-S®	Antimanic Agent	Morton Grove
Megestrol Acetate Oral Suspension	Megace®	Antineoplastic	Morton Grove
Metoclopramide HCl Oral Solution	Reglan®	Prokinetic Agent	Morton Grove
Myphetane DX Cough Syrup	Dimetane-DX®	Antitussive/Antihistamine/Decongestant	Morton Grove
Nystatin Oral Suspension	Mycostatin®	Antifungal	Morton Grove
Ondansetron Injection	Zofran®	Antinauseant/Antiemetic	Wockhardt USA
Oxybutynin Chloride Syrup	Ditropan®	Antispasmodic/Anticholinergic	Morton Grove
Phenytoin Oral Suspension	Dilantin®	Anticonvulsant	Morton Grove
Phenytoin Sodium Extended Capsules	Dilantin®	Anticonvulsant	Wockhardt USA
Prednisolone Sodium Phosphate Oral Solution	Orapred®	Corticosteroid	Morton Grove
Promethazine Syrup Plain	Phenergan®	Antihistamine	Morton Grove
Promethazine w/Codeine Cough Syrup	Phenergan w/Codeine®	Antihistamine/Antitussive	Morton Grove
Promethazine w/DM Cough Syrup	Phenergan w/DM®	Antihistamine/Antitussive	Morton Grove
Ranitidine Tablets	Zantac®	Histamine H2-Receptor Antagonist	Wockhardt USA
Selenium Sulfide Lotion	Selsun®	Antifungal	Morton Grove
Sertraline HCl Tablets	Zoloft®	Antidepressant	Wockhardt USA
Terbinafine HCl Tablets	Lamisil®	Antifungal	Wockhardt USA
Triamcinolone Acetonide Lotion	Kenalog®	Corticosteroid	Morton Grove
Valproic Acid Syrup	Depakene®	Anticonvulsant	Morton Grove
Zolpidem Tartrate Tablets	Ambien®	Sedative	Wockhardt USA
Zonisamide Capsules	Zonegran®	Anticonvulsant	Wockhardt USA

Wockhardt USA & Morton Grove Pharmaceuticals
Product List

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
60432-245-04	Acetaminophen & Codeine Phosphate Oral Solution	120/12mg per 5mL	118 mL	87-006	AA	Tylenol w/Codeine	Amber solution with cherry flavor	N/A	Morton Grove
60432-245-16	Acetaminophen & Codeine Phosphate Oral Solution	120/12mg per 5mL	473 mL	87-006	AA	Tylenol w/Codeine	Amber solution with cherry flavor	N/A	Morton Grove
60432-741-15	Acetic Acid Otic Solution	2%	15 mL	40-166	AT	VoSol	Colorless solution	N/A	Morton Grove
60432-093-16	Amantadine HCl Syrup	50mg/5mL	473 mL	75-060	AA	Symmetrel	Colorless to pale yellow syrup with raspberry flavor	N/A	Morton Grove
64679-421-01	Amlodipine Besylate Tablets	2.5 mg	90	78-500	AB	Norvasc	White to off-white, triangle-shaped tablet	W 421	Wockhardt USA
64679-422-01	Amlodipine Besylate Tablets	5 mg	90	78-500	AB	Norvasc	White to off-white, caplet-shaped tablet	W 422	Wockhardt USA
64679-422-02	Amlodipine Besylate Tablets	5 mg	1000	78-500	AB	Norvasc	White to off-white, caplet-shaped tablet	W 422	Wockhardt USA
64679-423-01	Amlodipine Besylate Tablets	10 mg	90	78-500	AB	Norvasc	White to off-white, round tablet	W 423	Wockhardt USA
64679-423-02	Amlodipine Besylate Tablets	10 mg	1000	78-500	AB	Norvasc	White to off-white, round tablet	W 423	Wockhardt USA
64679-961-05	Azithromycin Tablets	250 mg	6 x 3	65-404	AB	Zithromax	White, oval-shaped tablet	W 961	Wockhardt USA
64679-961-01	Azithromycin Tablets	250 mg	30	65-404	AB	Zithromax	White, oval-shaped tablet	W 961	Wockhardt USA
64679-964-05	Azithromycin Tablets	500 mg	3 x 3	65-405	AB	Zithromax	White, oval-shaped tablet	W 964	Wockhardt USA
64679-964-01	Azithromycin Tablets	500 mg	30	65-405	AB	Zithromax	White, oval-shaped tablet	W 964	Wockhardt USA
64679-962-01	Azithromycin Tablets	600 mg	30	65-406	AB	Zithromax	White, oval-shaped tablet	W 962	Wockhardt USA
64679-965-01	Bethanechol Chloride Tablets	5 mg	100	40-532	AA	Urecholine	White, oval-shaped, scored tablet	W 965	Wockhardt USA
64679-966-01	Bethanechol Chloride Tablets	10 mg	100	40-533	AA	Urecholine	Pink, oval-shaped, scored tablet	W 966	Wockhardt USA
64679-967-01	Bethanechol Chloride Tablets	25 mg	100	40-534	AA	Urecholine	Light yellow, oval-shaped, scored tablet	W 967	Wockhardt USA
64679-968-01	Bethanechol Chloride Tablets	50 mg	100	40-518	AA	Urecholine	Yellow, oval-shaped, scored tablet	W 968	Wockhardt USA
64679-902-01	Captopril Tablets	12.5 mg	100	74-532	AB	Capoten	White, round, scored tablet	W 902	Wockhardt USA
64679-902-02	Captopril Tablets	12.5 mg	1000	74-532	AB	Capoten	White, round, scored tablet	W 902	Wockhardt USA
64679-903-01	Captopril Tablets	25 mg	100	74-532	AB	Capoten	White, round, double-scored tablet	W 903	Wockhardt USA
64679-903-02	Captopril Tablets	25 mg	1000	74-532	AB	Capoten	White, round, double-scored tablet	W 903	Wockhardt USA
64679-904-01	Captopril Tablets	50 mg	100	74-532	AB	Capoten	White, round, scored tablet	W 904	Wockhardt USA
64679-904-02	Captopril Tablets	50 mg	1000	74-532	AB	Capoten	White, round, scored tablet	W 904	Wockhardt USA
64679-905-01	Captopril Tablets	100 mg	100	74-532	AB	Capoten	White, round, scored tablet	W 905	Wockhardt USA
60432-129-16	Carbamazepine Suspension	100mg/5mL	450 mL	75-714	AB	Tegretol	Yellow-orange suspension with citrus-vanilla flavor	N/A	Morton Grove
64679-986-01	Cefotaxime for Injection	1 g	1	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA
64679-986-02	Cefotaxime for Injection	1 g	10	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA

Wockhardt USA & Morton Grove Pharmaceuticals
Product List

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-986-03	Cefotaxime for Injection	1 g	25	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA
64679-986-04	Cefotaxime for Injection	1 g	50	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA
64679-712-03	Cefprozil Tablets	250 mg	100	65-428	AB	Cefzil	White, film-coated, capsule-shaped tablet	W 712	Wockhardt USA
64679-713-01	Cefprozil Tablets	500 mg	50	65-428	AB	Cefzil	White, film-coated, capsule-shaped tablet	W 713	Wockhardt USA
64679-713-03	Cefprozil Tablets	500 mg	100	65-428	AB	Cefzil	White, film-coated, capsule-shaped tablet	W 713	Wockhardt USA
64679-701-01	Ceftriaxone for Injection	250 mg	1	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-701-02	Ceftriaxone for Injection	250 mg	10	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-701-03	Ceftriaxone for Injection	250 mg	25	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-702-01	Ceftriaxone for Injection	500 mg	1	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-702-02	Ceftriaxone for Injection	500 mg	10	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-983-01	Ceftriaxone for Injection	1 g	1	65-180	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-983-02	Ceftriaxone for Injection	1 g	10	65-180	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-703-02	Ceftriaxone for Injection	2 g	1	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-703-01	Ceftriaxone for Injection	2 g	10	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-921-01	Cefuroxime Axetil Tablets	250 mg	20	65-166	AB	Ceftin	White, film-coated, round, unscored tablet	W 921	Wockhardt USA
64679-921-02	Cefuroxime Axetil Tablets	250 mg	60	65-166	AB	Ceftin	White, film-coated, round, unscored tablet	W 921	Wockhardt USA
64679-922-01	Cefuroxime Axetil Tablets	500 mg	20	65-166	AB	Ceftin	White, film-coated, capsule-shaped, unscored tablet	W 922	Wockhardt USA
64679-922-02	Cefuroxime Axetil Tablets	500 mg	60	65-166	AB	Ceftin	White, film-coated, capsule-shaped, unscored tablet	W 922	Wockhardt USA
60432-007-08	Cimetidine HCl Oral Solution	300mg/5mL	237 mL	74-757	AA	Tagamet	Clear to light orange solution with peach flavor	N/A	Morton Grove
64679-954-01	Clarithromycin Tablets	250 mg	60	65-266	AB	Biaxin	White, film-coated, oval-shaped tablet	W 954	Wockhardt USA
64679-949-01	Clarithromycin Tablets	500 mg	60	65-266	AB	Biaxin	White, film-coated, oval-shaped tablet	W 949	Wockhardt USA
60432-133-25	Clobetasol Topical Solution, USP	0.05%	25 mL	75-205	AT	Temovate	Colorless solution	N/A	Morton Grove
60432-133-50	Clobetasol Topical Solution, USP	0.05%	50 mL	75-205	AT	Temovate	Colorless solution	N/A	Morton Grove
60432-140-50	Cyclosporine Oral Solution	100mg/mL	50 mL	65-133	AB	Sandimmune	Clear yellow solution with olive flavor	N/A	Morton Grove
60432-466-08	Dexamethasone Elixir	0.5mg/5mL	237 mL	88-254	AA	Decadron	Clear red elixir with raspberry flavor	N/A	Morton Grove
60432-539-16	Dexchlorpheniramine Maleate Oral Solution	2mg/5mL	473 mL	88-251	AA	Polaramine	Red-orange syrup with orange flavor	N/A	Morton Grove
60432-651-04	Doxepin HCl Oral Solution	10mg/mL	118 mL	71-918	AA	Sinequan	Colorless solution with peppermint flavor	N/A	Morton Grove
64679-923-02	Enalapril Maleate Tablets	2.5 mg	100	75-483	AB	Vasotec	White, round, scored tablet	W 923	Wockhardt USA

Wockhardt USA & Morton Grove Pharmaceuticals
Product List

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-923-03	Enalapril Maleate Tablets	2.5 mg	1000	75-483	AB	Vasotec	White, round, scored tablet	W 923	Wockhardt USA
64679-924-02	Enalapril Maleate Tablets	5 mg	100	75-483	AB	Vasotec	White, round, scored tablet	W 924	Wockhardt USA
64679-924-03	Enalapril Maleate Tablets	5 mg	1000	75-483	AB	Vasotec	White, round, scored tablet	W 924	Wockhardt USA
64679-925-02	Enalapril Maleate Tablets	10 mg	100	75-483	AB	Vasotec	Light salmon, round, unscored tablet	W 925	Wockhardt USA
64679-925-03	Enalapril Maleate Tablets	10 mg	1000	75-483	AB	Vasotec	Light salmon, round, unscored tablet	W 925	Wockhardt USA
64679-926-02	Enalapril Maleate Tablets	20 mg	100	75-483	AB	Vasotec	Light beige, round, unscored tablet	W 926	Wockhardt USA
64679-926-03	Enalapril Maleate Tablets	20 mg	1000	75-483	AB	Vasotec	Light beige, round, unscored tablet	W 926	Wockhardt USA
60432-671-60	Erythromycin Topical Solution	2%	60 mL	62-825	AT	Eryderm	Colorless solution	N/A	Morton Grove
64679-936-01	Famotidine Tablets	20 mg	30	75-786	AB	Pepcid	Beige, barrel-shaped, unscored tablet	W 936	Wockhardt USA
64679-936-02	Famotidine Tablets	20 mg	100	75-786	AB	Pepcid	Beige, barrel-shaped, unscored tablet	W 936	Wockhardt USA
64679-936-03	Famotidine Tablets	20 mg	1000	75-786	AB	Pepcid	Beige, barrel-shaped, unscored tablet	W 936	Wockhardt USA
64679-937-01	Famotidine Tablets	40 mg	30	75-786	AB	Pepcid	White, barrel-shaped, unscored tablet	W 937	Wockhardt USA
64679-937-02	Famotidine Tablets	40 mg	100	75-786	AB	Pepcid	White, barrel-shaped, unscored tablet	W 937	Wockhardt USA
64679-937-03	Famotidine Tablets	40 mg	1000	75-786	AB	Pepcid	White, barrel-shaped, unscored tablet	W 937	Wockhardt USA
60432-162-04	Fluoxetine Oral Solution	20mg/5mL	118 mL	75-514	AA	Prozac	Colorless to pale yellow solution with slight mint flavor	N/A	Morton Grove
64679-729-01	Fosphenytoin Sodium Injection	50 mg PE/mL	2 mL x 25	78-137	AP	Cerebyx	Colorless/pale yellow, clear solution in vial (100mg PE in 2mL; PE=phenytoin sodium equivalents)	N/A	Wockhardt USA
64679-730-01	Fosphenytoin Sodium Injection	50 mg PE/mL	10 mL x 10	78-137	AP	Cerebyx	Colorless/pale yellow, clear solution in vial (500mg PE in 10mL; PE=phenytoin sodium equivalents)	N/A	Wockhardt USA
60432-613-60	Furosemide Oral Solution	10mg/mL	60 mL	70-655	AA	Lasix	Yellow solution with orange flavor	N/A	Morton Grove
60432-613-04	Furosemide Oral Solution	10mg/mL	118 mL	70-655	AA	Lasix	Yellow solution with orange flavor	N/A	Morton Grove
60432-038-16	Generlac Solution	10gm/15mL	473 mL	74-603	AA	Cephulac	Colorless to yellow solution with no flavor	N/A	Morton Grove
60432-038-64	Generlac Solution	10gm/15mL	1892 mL	74-603	AA	Cephulac	Colorless to yellow solution with no flavor	N/A	Morton Grove
64679-662-01	Granisetron HCl Injection	0.1 mg/mL	1 mL x 5	78-566	AP	Kytril	Clear, colorless solution in vial	N/A	Wockhardt USA
60432-455-16	Hydrocodone and Homatropine Syrup	5/1.5mg per 5mL	473 mL	88-008	AA	Hycodan	Red syrup with cherry flavor	N/A	Morton Grove
60432-150-04	Hydroxyzine HCl Syrup	10mg/5mL	118 mL	87-294	AA	Atarax	Colorless syrup with peppermint flavor	N/A	Morton Grove
60432-150-16	Hydroxyzine HCl Syrup	10mg/5mL	473 mL	87-294	AA	Atarax	Colorless syrup with peppermint flavor	N/A	Morton Grove
64679-757-03	Ketorolac Tromethamine Injection	15mg/mL	1 mL x 1	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-757-02	Ketorolac Tromethamine Injection	15mg/mL	1 mL x 10	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-757-01	Ketorolac Tromethamine Injection	15mg/mL	1 mL x 25	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA

Wockhardt USA & Morton Grove Pharmaceuticals
Product List

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-758-04	Ketorolac Tromethamine Injection	30mg/mL	1 mL x 10	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-01	Ketorolac Tromethamine Injection	30mg/mL	1 mL x 25	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-05	Ketorolac Tromethamine Injection	30mg/mL	2 mL x 1	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-06	Ketorolac Tromethamine Injection	30mg/mL	2 mL x 10	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-02	Ketorolac Tromethamine Injection	30mg/mL	2 mL x 25	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
60432-037-08	Lactulose Solution	10gm/15mL	237 mL	74-602	AA	Chronulac	Colorless to pale yellow solution with no flavor	N/A	Morton Grove
60432-037-32	Lactulose Solution	10gm/15mL	946 mL	74-602	AA	Chronulac	Colorless to pale yellow solution with no flavor	N/A	Morton Grove
60432-464-00	Lidocaine HCl Oral Solution	2%	100 mL	87-872	AT	Xylocaine	Colorless to pale yellow solution with cherry flavor	N/A	Morton Grove
60432-465-50	Lidocaine HCL Topical Solution	4%	50 mL	87-881	AT	Xylocaine	Colorless solution	N/A	Morton Grove
60432-833-60	Lindane Lotion	1%	60 mL	88-190	AT	Kwell	White to pale yellow lotion	N/A	Morton Grove
60432-834-60	Lindane Shampoo	1%	60 mL	88-191	AT	Kwell	Pale yellow shampoo	N/A	Morton Grove
64679-927-01	Lisinopril Tablets	2.5 mg	100	78-402	AB	Zestril	White to off-white, round, unscored tablet	W	Wockhardt USA
64679-927-05	Lisinopril Tablets	2.5 mg	500	78-402	AB	Zestril	White to off-white, round, unscored tablet	W	Wockhardt USA
64679-928-01	Lisinopril Tablets	5 mg	100	78-402	AB	Zestril	White to off-white, round, scored tablet	W 928	Wockhardt USA
64679-928-06	Lisinopril Tablets	5 mg	1000	78-402	AB	Zestril	White to off-white, round, scored tablet	W 928	Wockhardt USA
64679-929-01	Lisinopril Tablets	10 mg	100	78-402	AB	Zestril	White to off-white, round, unscored tablet	W 929	Wockhardt USA
64679-929-06	Lisinopril Tablets	10 mg	1000	78-402	AB	Zestril	White to off-white, round, unscored tablet	W 929	Wockhardt USA
64679-941-01	Lisinopril Tablets	20 mg	100	78-402	AB	Zestril	Light yellow, round, unscored tablet	W 941	Wockhardt USA
64679-941-06	Lisinopril Tablets	20 mg	1000	78-402	AB	Zestril	Light yellow, round, unscored tablet	W 941	Wockhardt USA
64679-953-01	Lisinopril Tablets	30 mg	100	78-402	AB	Zestril	Light red, round, unscored tablet	W 953	Wockhardt USA
64679-953-05	Lisinopril Tablets	30 mg	500	78-402	AB	Zestril	Light red, round, unscored tablet	W 953	Wockhardt USA
64679-942-01	Lisinopril Tablets	40 mg	100	78-402	AB	Zestril	Light brown, round, unscored tablet	W 942	Wockhardt USA
64679-942-02	Lisinopril Tablets	40 mg	1000	78-402	AB	Zestril	Light brown, round, unscored tablet	W 942	Wockhardt USA
60432-616-16	Lithium Citrate Syrup	300mg/5mL	473 mL	70-755	AA	Cibalith-S	Colorless syrup with raspberry flavor	N/A	Morton Grove
60432-126-08	Megestrol Acetate Oral Suspension	40mg/mL	237 mL	76-721	AB	Megace	Creamy white suspension with lemon-lime flavor	N/A	Morton Grove
60432-126-16	Megestrol Acetate Oral Suspension	40mg/mL	473 mL	76-721	AB	Megace	Creamy white suspension with lemon-lime flavor	N/A	Morton Grove
60432-622-16	Metoclopramide HCl Oral Solution	5mg/5mL	473 mL	74-703	AA	Reglan	Orange syrup with butterscotch flavor	N/A	Morton Grove
60432-482-16	Myphetane DX Cough Syrup (Pseudoephed; Dextrometh; Bromphen)	30/10/2mg per 5mL	473 mL	88-811	AA	Dimetane-DX	Clear, light pink syrup with butterscotch flavor	N/A	Morton Grove

Wockhardt USA & Morton Grove Pharmaceuticals
Product List

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
60432-537-60	Nystatin Oral Suspension	100,000 units/mL	60 mL	62-512	AA	Mycostatin	Light creamy yellow suspension with fruit flavor	N/A	Morton Grove
60432-537-16	Nystatin Oral Suspension	100,000 units/mL	473 mL	62-512	AA	Mycostatin	Light creamy yellow suspension with fruit flavor	N/A	Morton Grove
64679-726-01	Ondansetron Injection	2mg/mL	2 mL x 5	77-716	AP	Zofran	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-727-01	Ondansetron Injection	2mg/mL	20 mL x 1	77-757	AP	Zofran	Clear, colorless solution in vial	N/A	Wockhardt USA
60432-092-16	Oxybutynin Chloride Syrup	5mg/5mL	473 mL	74-868	AA	Ditropan	Light aqua syrup with raspberry flavor	N/A	Morton Grove
60432-131-08	Phenytoin Oral Suspension	125mg/5mL	237 mL	40-420	AB	Dilantin	Orange suspension with orange-vanilla flavor	N/A	Morton Grove
64679-720-01	Phenytoin Sodium Extended Capsules	100 mg	100	40-732	AB	Dilantin	Orange body and cap	W 720	Wockhardt USA
64679-720-02	Phenytoin Sodium Extended Capsules	100 mg	1000	40-732	AB	Dilantin	Orange body and cap	W 720	Wockhardt USA
60432-212-08	Prednisolone Sodium Phosphate Oral Solution	15mg/5mL	237 mL	76-895	AA	Orapred	Red solution with cherry flavor	N/A	Morton Grove
60432-608-04	Promethazine Syrup Plain	6.25mg/5mL	118 mL	87-953	AA	Phenergan	Green syrup with tropical fruit flavor	N/A	Morton Grove
60432-608-16	Promethazine Syrup Plain	6.25mg/5mL	473 mL	87-953	AA	Phenergan	Green syrup with tropical fruit flavor	N/A	Morton Grove
60432-606-16	Promethazine w/Codeine Cough Syrup	6.25/10mg per 5mL	473 mL	88-875	AA	Phenergan w/Codeine	Clear purple syrup with raspberry flavor	N/A	Morton Grove
60432-604-04	Promethazine w/DM Cough Syrup	6.25/15mg per 5mL	118 mL	88-864	AA	Phenergan w/DM	Clear yellow syrup with pineapple flavor	N/A	Morton Grove
60432-604-16	Promethazine w/DM Cough Syrup	6.25/15mg per 5mL	473 mL	88-864	AA	Phenergan w/DM	Clear yellow syrup with pineapple flavor	N/A	Morton Grove
64679-906-01	Ranitidine Tablets	150 mg	60	75-208	AB	Zantac	White, film coated, six-sided, unscored, tablet	W 906	Wockhardt USA
64679-906-06	Ranitidine Tablets	150 mg	100	75-208	AB	Zantac	White, film coated, six-sided, unscored, tablet	W 906	Wockhardt USA
64679-906-03	Ranitidine Tablets	150 mg	500	75-208	AB	Zantac	White, film coated, six-sided, unscored, tablet	W 906	Wockhardt USA
64679-907-01	Ranitidine Tablets	300 mg	30	75-208	AB	Zantac	White, film coated, capsule-shaped, unscored, tablet	W 907	Wockhardt USA
64679-907-04	Ranitidine Tablets	300 mg	100	75-208	AB	Zantac	White, film coated, capsule-shaped, unscored, tablet	W 907	Wockhardt USA
64679-907-02	Ranitidine Tablets	300 mg	250	75-208	AB	Zantac	White, film coated, capsule-shaped, unscored, tablet	W 907	Wockhardt USA
60432-528-04	Selenium Sulfide Lotion	2.5%	118 mL	88-228	AT	Selsun	Beige lotion	N/A	Morton Grove
64679-752-01	Sertraline HCl Tablets	50 mg	100	78-403	AB	Zoloft	Blue, film-coated, capsule-shaped, scored tablet	W 752	Wockhardt USA
64679-752-04	Sertraline HCl Tablets	50 mg	500	78-403	AB	Zoloft	Blue, film-coated, capsule-shaped, scored tablet	W 752	Wockhardt USA
64679-752-07	Sertraline HCl Tablets	50 mg	1000	78-403	AB	Zoloft	Blue, film-coated, capsule-shaped, scored tablet	W 752	Wockhardt USA
64679-753-01	Sertraline HCl Tablets	100 mg	100	78-403	AB	Zoloft	Yellow, film-coated, capsule-shaped, scored tablet	W 753	Wockhardt USA
64679-753-04	Sertraline HCl Tablets	100 mg	500	78-403	AB	Zoloft	Yellow, film-coated, capsule-shaped, scored tablet	W 753	Wockhardt USA
64679-753-07	Sertraline HCl Tablets	100 mg	1000	78-403	AB	Zoloft	Yellow, film-coated, capsule-shaped, scored tablet	W 753	Wockhardt USA
64679-209-01	Terbinafine HCl Tablets	250 mg	30	77-533	AB	Lamisil	White, round, unscored tablet	IG 209	Wockhardt USA

Wockhardt USA & Morton Grove Pharmaceuticals
Product List

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-209-02	Terbinafine HCl Tablets	250 mg	100	77-533	AB	Lamisil	White, round, unscored tablet	IG 209	Wockhardt USA
60432-560-60	Triamcinolone Acetonide Lotion	0.025%	60 mL	88-450	AT	Kenalog	Creamy white lotion	N/A	Morton Grove
60432-561-60	Triamcinolone Acetonide Lotion	0.1%	60 mL	88-451	AT	Kenalog	Creamy white lotion	N/A	Morton Grove
60432-621-16	Valproic Acid Syrup	250mg/5mL	473 mL	70-868	AA	Depakene	Red syrup with cherry flavor	N/A	Morton Grove
64679-714-01	Zolpidem Tartrate Tablets	5 mg	100	78-426	AB	Ambien	Pink, film-coated, capsule-shaped tablet	W 714	Wockhardt USA
64679-714-04	Zolpidem Tartrate Tablets	5 mg	500	78-426	AB	Ambien	Pink, film-coated, capsule-shaped tablet	W 714	Wockhardt USA
64679-715-01	Zolpidem Tartrate Tablets	10 mg	100	78-426	AB	Ambien	White, film-coated, capsule-shaped tablet	W 715	Wockhardt USA
64679-715-04	Zolpidem Tartrate Tablets	10 mg	500	78-426	AB	Ambien	White, film-coated, capsule-shaped tablet	W 715	Wockhardt USA
64679-945-01	Zonisamide Capsules	25 mg	100	77-636	AB	Zonegran	White, opaque body and white opaque cap	W 945	Wockhardt USA
64679-946-01	Zonisamide Capsules	50 mg	100	77-636	AB	Zonegran	White, opaque body and grey opaque cap	W 946	Wockhardt USA
64679-990-01	Zonisamide Capsules	100 mg	100	77-636	AB	Zonegran	White opaque body and orange opaque cap	W 990	Wockhardt USA

EXHIBIT 3

MORTON GROVE PHARMACEUTICALS

Commitment to Public Health and Safety

Morton Grove Pharmaceuticals, Inc. (MGP) is a specialty pharmaceutical company headquartered in Illinois, and is one of the leading manufacturers of generic prescription oral liquid and topical medications in the U.S. The company employs more than 260 professionals in the areas of research and development, compliance, regulatory affairs, manufacturing, distribution, and sales. As the sole U.S. manufacturer of lindane lotion and lindane shampoo, MGP has worked with the Food and Drug Administration (FDA) to advance the safety and usefulness of this second-line medication.

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

A portfolio of therapies that benefit public health

A strong commitment to quality manufacturing and research and development has enabled MGP to help lead the industry in providing the healthcare community and the public with affordable generic liquid prescription medications.

- More than 65 different prescription therapies are owned and developed by MGP—the majority are cost-saving generics
- Core therapeutics are manufactured at MGP's 125,000 square foot, state-of-the-art facility located in Morton Grove, Illinois, with another research facility in Vernon Hills, Illinois
- Research and development efforts are supported by the innovation of more than 30 R&D scientists and more than 260 employees overall

MGP therapies are used in many different areas of medicine

Allergy	Infectious disease
Cardiology	Internal medicine
Dermatology	Neurology
Gastroenterology	Pediatric psychiatry
Immunology	Transplant medicine

Continued investments in lindane safety

MGP recognizes the public health need to preserve lindane as a second-line therapy and has already taken important measures to minimize the risk for product misuse. In consultation with regulatory experts, MGP has also initiated an extensive and rigorous lindane clinical research program. This ongoing investment is designed to further enhance the benefit-safety balance of lindane medications.

Commitment to Public Health and Safety | Lindane Prescribing Information | FDA Information on Lindane

Lindane Prescribing INFORMATION

Lindane Lotion for Scabies

Package insert (pdf)
Medication guide (pdf)

Lindane Shampoo for Lice

Package insert (pdf)
Medication guide (pdf)

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

LINDANE LOTION, USP 1%
Rx only

WARNINGS:

Lindane Lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies. (See INDICATIONS AND USAGE.)

Neurologic Toxicity

Seizures and deaths have been reported following Lindane Lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane Lotion should be used with caution for infants, children, the elderly, and individuals with other skin conditions (e.g., atopic dermatitis, psoriasis) and in those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Contraindications

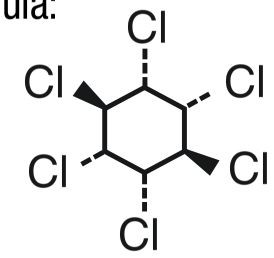
Lindane Lotion is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

Proper Use

Instruct patients on the proper use of Lindane Lotion, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of scabies and is not necessarily an indication for retreatment with Lindane Lotion. (See DOSAGE AND ADMINISTRATION.)

DESCRIPTION

Lindane Lotion, USP 1%, is an ectoparasiticide and ovicide. In addition to the active ingredient, lindane, it contains 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylene glycol, propylparaben, purified water, stearic acid and trolamine to form a lotion. The pH range is between 6.5 and 8.5. Lindane is the gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane having the following structural formula:



$C_6H_6Cl_6$ M.W. 290.83

004

CLINICAL PHARMACOLOGY

Lindane Lotion, USP 1%, is an ectoparasiticide and ovicide effective against *Sarcoptes scabiei* (scabies). Lindane exerts its parasiticidal action by being directly absorbed into the parasites and their ova. Feldmann and Maibach[1] reported approximately 10% systemic absorption of a lindane acetone solution when applied to the forearm of human subjects and left in place for 24 hours. This vehicle was different from the approved product and the percutaneous penetration of lindane is dependent on the vehicle. Therefore, the clinical significance of these observations is unknown. Dale, et al[2] reported a blood level of 290 ng/mL associated with convulsions following the accidental ingestion of a lindane-containing product. Ginsburg[3] found the greatest peak blood level of 64 ng/mL, 6 hours after total body application of Lindane Lotion in 1 of 8 non-scabietic pediatric patients. The half-life in blood was determined to be approximately 18 hours.

Data available in the literature suggest that lindane has a rapid distribution phase followed by a longer β-elimination phase.[1, 2, 3]

INDICATIONS AND USAGE

Lindane Lotion is indicated for the treatment of scabies (infestations of *Sarcoptes scabei*) only in patients who:

1. cannot tolerate other approved therapies, or
2. have failed treatment with other approved therapies.

Lindane Lotion should be used in the context of an overall scabies management program that includes:

- Microscopic evaluation of skin scrapings to confirm the diagnosis.
- Evaluation and treatment of sexual contacts simultaneously. Sexual contacts should be prescribed Lindane Lotion only if they either have failed to respond to adequate doses of other approved therapies or are intolerant of other approved therapies.
- Washing of all recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels in very hot water or dry-cleaned.

Caregivers applying this product to patients should wear gloves less permeable to Lindane, such as nitrile, latex with neoprene, or sheer vinyl, and thoroughly clean hands after application. Natural latex gloves should be avoided because they are more permeable to Lindane.

Lindane Lotion does not prevent infestation or reinfestation and should not be used to ward off a possible infestation.

CONTRAINDICATIONS

Lindane Lotion is contraindicated for premature infants because their skin may be more permeable than that of full term infants

and their liver enzymes may not be sufficiently developed to metabolize Lindane.

Lindane Lotion is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.

Lindane Lotion is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

WARNINGS (See boxed WARNINGS.)

Seizures and deaths have been reported following Lindane Lotion's use with repeat or prolonged application, but also in rare cases following a single application reportedly used according to directions. It is not known how soon after application of a single dose of Lindane Lotion that a second dose of Lindane Lotion can be safely applied.

There have been cases of adverse events reported for Lindane Lotion and Lindane Shampoo in which a serious outcome (hospitalization, disability or death) has occurred.[4] In approximately 20% of the total reported cases, Lindane Lotion and Shampoo were reported to have been used according to the labeled directions. Of these cases, thirteen deaths were reported, many cases which were remote from the time of actual Lindane use. Lindane toxicity, verified by autopsy was the cause of one infant's death, was the cause of death reported for an adult who ingested it orally in a successful suicide. The direct causes of death for the other cases were attributed to reasons other than Lindane. Most of these adverse events occurred with Lindane Lotion.

Infants, children, the elderly, and individuals with other skin conditions and those who weigh < 110 lbs (50 kg) may be at greater risk of serious neurotoxicity. (See Pediatric Use and Geriatric Use.) Animal studies have shown increased susceptibility to neurologic adverse events in younger animals. Children have a larger body surface area to volume ratio that may result in a proportionately larger systemic exposure.

Careful consideration should be given before prescribing Lindane Lotion to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold. (See PRECAUTIONS: Drug Interactions.)

Patients should be instructed on proper use of Lindane Lotion, especially the amount to apply, how long to leave the lotion on, and the need to avoid retreatment. Patients should be informed that itching may occur, and even worsen, after the successful killing of scabies. Repeat treatment is usually not necessary.

A Lindane Lotion Medication Guide must be given to the patient each time Lindane Lotion is dispensed, as required by law.

PRECAUTIONS

General: Care should be taken to avoid contact with the eyes. If such contact occurs, eyes should be immediately flushed with water. If irritation or sensitization occurs, the patient should be advised to consult a physician.

Information for Patients (and Caregivers):

- **This product can be poisonous if misused.**
- **Other important information is found in the Medication Guide, which by law, must be dispensed with Lindane Lotion.**
- If someone other than the patient will be applying Lindane Lotion to the patient, they should wear less permeable gloves such as nitrile, latex with neoprene, or sheer vinyl, and thoroughly clean their hands after application. Natural latex gloves should be avoided because they are more permeable to lindane.
- If the person applying Lindane Lotion could be pregnant, contact with Lindane Lotion should be avoided as much as possible.
- If the patient could be pregnant, other treatments may be preferable.
- Lindane Lotion should be used for scabies only.
- The skin should be clean and without any other lotion, cream, or oil on it. Oils can make the Lindane Lotion go through the skin faster and possibly increase the risk of neurotoxicity (e.g., seizures).
- Wait at least 1 hour after bathing or showering before putting Lindane Lotion on the skin. Wet or warm skin can make the Lindane Lotion go through skin faster.
- Information for Use:
  - Shake Lindane Lotion well.
  - Put Lindane Lotion under fingernails after trimming the fingernails short, because scabies are very likely to remain there. A toothbrush can be used to apply the Lindane Lotion under the fingernails. Immediately after use, the toothbrush should be wrapped in paper and thrown away. Use of the same brush in the mouth could lead to poisoning.
  - Use only a single application, applied as a very thin layer over all skin from the neck down.
  - Close the bottle with the leftover Lindane Lotion and immediately throw it away in a trash can out of the reach of children.
  - Do not use any covering over the applied Lindane Lotion that does not breathe, like diapers with plastic lining, plastic clothes, tight clothes, or blankets.
  - Wash the Lindane Lotion completely off after 8 to 12 hours. Never leave Lindane Lotion on the skin for more than 12 hours. Warm, but not hot water can be used. Lindane Lotion will not kill any more scabies after 8 to 12 hours, but may cause serious

health problems.

- Keep Lindane Lotion away from mouth and eyes. If contact with eyes occurs, immediately flush eyes with water. Do not use if you have open wounds, cuts or sores that are present, unless specifically directed by the prescribing physician.
- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- The patient may still itch after using Lindane Lotion. This does not mean the medicine did not work. Even after all the scabies (bugs) are dead, they can still make the skin itch for a few weeks. Lindane Lotion sometimes makes this itch even worse. Other treatments can be used to soothe the itch. Do not use more Lindane Lotion.
- The patient should contact the physician with any questions or concerns about his or her condition or use of the Lindane Lotion.

Drug Interactions: Oils may enhance absorption of Lindane, therefore, patients or caregivers applying Lindane Lotion should be warned about simultaneous use of creams, ointments, or oils. In addition, there are many drugs that may lower the seizure threshold, and Lindane Lotion should be prescribed with caution in patients taking these medications. Drugs that may lower the seizure threshold include, but are not limited to the following:

- Antipsychotics
- Antidepressants
- Theophylline
- Cyclosporine, mycophenolate mofetil, tacrolimus capsules
- Penicillins, imipenem, quinolone antibiotics
- Chloroquine sulfate, pyrimethamine
- Isoniazid
- Meperidine
- Radiographic contrast agents
- Centrally active anticholinesterases
- Methocarbamol

Carcinogenesis, Mutagenesis, and Fertility: Although no studies have been conducted with Lindane Lotion, numerous long-term feeding studies have been conducted in mice and rats to evaluate the carcinogenic potential of the technical grade of hexachlorocyclohexane as well as the alpha, beta, gamma (lindane) and delta isomers. Both oral and topical applications have been evaluated. Increased incidences of neoplasms were not clearly related to administration of lindane. The results of

mutagenicity tests in bacteria do not indicate that lindane is mutagenic. Lindane did not cause sister chromatid exchange in an *in vivo* assay. The number of spermatids in the testes of rats 2 weeks after oral administration of a single dose of 30 mg/kg body weight (12 times the estimated human exposure for scabies on a body surface area comparison and assuming 50% rat oral bioavailability and 10% human bioavailability) was significantly reduced compared to the control rats.

Pregnancy: Pregnancy Category C. All pregnancies have a risk of birth defect, loss, or other adverse event regardless of drug exposure. Predictions of fetal risk from drug exposure rely heavily on animal data. However, animal studies may fail to predict effects in humans or may overstate such risks. Even if human data are available, the data may not be sufficient to determine whether there is an increased risk to the fetus, and individual reports of adverse outcomes in pregnancy in association with a drug may not reflect a casual relationship.

Lindane Lotion should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Lotion in pregnant women. There are no known maternal or fetal health risks if the scabies is not treated. Lindane is lipophilic and may accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures to lindane during pregnancy. The relationship of the maternal exposures to the fetal outcome is unknown.

Animal data suggest that lindane exposure of the fetus may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug.

Data: When rats received lindane in the diet from day 6 of gestation through day 10 of lactation, reduced pup survival, decreased pup weight and decreased weight gains during lactation, increased motor activity and decreased motor activity habituation were seen in pups at 5.6 mg/kg (2 times the estimated human exposure) but not at 1.2 mg/kg. An increased number of stillborn pups was seen at 8 mg/kg, and increased pup mortality was seen at 5.6 mg/kg. No gross abnormalities were seen in this study or in a study in which rabbits received up to 20 mg/kg lindane by gavage on gestation day 6-18 (up to 10 times the human exposure on a body surface area comparison and assuming 50% rabbit oral bioavailability and 10% human bioavailability).

Nursing Mothers: Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding when Lindane Lotion is applied topically to the chest area. Nursing mothers who require treatment with Lindane Lotion should be advised of the potential risks and be counseled to avoid large areas of skin-to-skin contact with the infant while Lindane Lotion is applied, as well as to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use.

Pediatric Use: Animal data demonstrated increased risk of adverse events in the young across species. Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Lotion is applied to the body. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver. Lindane Lotion should be used with extreme caution in patients who weigh less than approximately 110 lbs (50 kg) and especially in infants. Lindane Lotion is indicated only for the treatment of scabies; patients with lice should use Lindane Shampoo according to the labeled instructions.

Geriatric Use: There have been no studies of Lindane Lotion in the elderly. There are four postmarketing reports of deaths in elderly patients who were treated for scabies with Lindane Lotion. Two patients died within 24 hours of Lindane Lotion application and the third patient died 41 days after application of Lindane Lotion, having suffered a seizure on the day of death. A fourth patient died of an unreported cause of death on the same day that Lindane Lotion treatment for scabies was administered.

ADVERSE REACTIONS

Lindane Lotion has been reported to cause central nervous system stimulation ranging from dizziness to seizures. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Lotion was used according to directions. Irritant dermatitis from contact with this product has also been reported. (See WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION.)

Postmarketing Experience: The following adverse reactions reflect additional postmarketing experience of Lindane Lotion. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria. The relationship of some of these events to Lindane therapy is unknown.

OVERDOSAGE

Contact the closest Poison Control Center in the event of suspected overdosage with Lindane Lotion.

If accidental ingestion occurs, prompt gastric lavage should be instituted. However, since oils enhance absorption, saline cathartics for intestinal evacuation should be given rather than oil laxatives. If central nervous system (CNS) manifestations occur, they may be antagonized by the administration of pentobarbital, phenobarbital, or diazepam.

DOSAGE AND ADMINISTRATION

Apply a thin layer of Lindane Lotion over all skin from the neck down. One ounce is sufficient for an average adult. Do not prescribe more than 2 ounces for larger adults. Apply only once. Wash off in 8 to 12 hours. Do not retreat. (See boxed WARNINGS.)

Patients should be provided specific information on use of product. (See PRECAUTIONS: Information for Patients and the Medication Guide.) Patients should be instructed on proper use of Lindane Lotion, especially the amount to apply, how long to leave on and the need to avoid retreatment. Patients should be informed that itching occurs after the successful killing of scabies (lice) and continued itching is not necessarily an indication for retreatment with Lindane Lotion.
A **Lindane Lotion Medication Guide** must be given to the patient each time Lindane Lotion is dispensed, as required by law. The Lindane Lotion Medication Guide is an important part of the risk management program for the patient.

HOW SUPPLIED

Lindane Lotion, USP 1% is supplied in patient-size 2 fl oz (60 mL) bottles.

SHAKE WELL BEFORE USING

Store at controlled room temperature, 15 ° - 30 °C (59 ° - 86 °F) [see USP].

REFERENCES

1. Feldmann, R.J. and Maibach, H.I., *Toxicol. Applied. Pharmacol.,* 28:126, 1974.
2. Dale, W.E., Curly, A. and Cueto, C. *Life Sci* 5:47*,* 1966.
3. Ginsburg, C.M., et al., *J. Pediatr.* 91:6, 998-1000*,* 1977.
4. FDA AERS database search, January 2003

Rx Only

Product No.: 8546

Manufactured By: Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053 A42-8546-60 REV. 06-05
Distributed By: Alliant Pharmaceuticals, Inc. Alpharetta, GA 30004

PHARMACIST—PATIENT MEDICATION GUIDE PROVIDED BELOW

MEDICATION GUIDE
Lindane (LIHN-dane) Lotion, USP 1%

You must read and follow <u>all</u> instructions before using Lindane Lotion. Read the information you get every time you

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or a family member get Lindane Lotion. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Lindane Lotion, ask your doctor or pharmacist.

What is the most important information I should know about Lindane Lotion?

Lindane Lotion is a poison if you do not use it the right way. Lindane Lotion goes through your skin and may affect your brain and nerves. Lindane Lotion can cause seizures, also called convulsions, "fits" or epilepsy.

- Seizures and death can happen in people who use Lindane Lotion too much or too often.
- Seizures can happen in some people even if they use Lindane Lotion exactly as directed.

If you or a family member has a seizure while using Lindane Lotion, get emergency help right away.

- Do not use Lindane Lotion unless:
  - You have scabies and were treated with another medicine that did not work for you, or
  - You cannot use other safer medicines to treat your scabies.
- Do not use Lindane Lotion more than 1 time to treat an attack of scabies. Do not use Lindane Lotion to treat a second attack of scabies that comes soon after the first episode. Using it more than 1 time can cause seizures and death. No one knows a safe time to reuse Lindane Lotion. Even if you still itch after using Lindane Lotion, do not use more or use it again. Scabies (bugs) can make your skin itch for a few weeks even after all of the bugs are dead.
- Do not use more Lindane Lotion than your doctor tells you.
- Do not keep Lindane Lotion on your skin for more than 8 to 12 hours.
- Do not put Lindane Lotion in your mouth because it is a poison if taken by mouth. If you get Lindane Lotion in your mouth or swallow Lindane Lotion, call your area Poison Control Center right away and get emergency help.

What is Lindane Lotion?

Lindane Lotion is a medicine that is used to treat scabies. It kills scabies and their eggs. Scabies are very small bugs that crawl under your skin, lay eggs, and cause severe itching. Lindane Lotion goes through your skin and kills the scabies and their eggs. Lindane Lotion is used only after safer medicines have not made your scabies go away. The only time Lindane Lotion is used first is when someone cannot use safer medicines, which may include permethrin and crotamiton.

Lindane Lotion is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds, use

Lindane Lotion only if your doctor thinks it is really needed. People who weigh less than 110 pounds and the elderly have higher chances for side effects because more lindane may go through their skin.

Who should not use Lindane Lotion?

Do not use Lindane Lotion:

- if you do not have scabies. Lindane Lotion does not stop you from getting scabies. Lindane Lotion only kills the scabies you already have.
- if you have or have ever had seizures, also called convulsions, “fits” or epilepsy, especially if they have been hard to control.
- if you used Lindane Lotion in the past few months. You should see your doctor if you think you need another treatment.
- unless it is the only medicine you can use for scabies.
- if you had a bad reaction to Lindane Lotion before. **Do not use Lindane Lotion again.**
- if you have open sores or crusted (scabby) sores on your skin, or lots of broken skin.
- if you have head or body lice. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Lotion or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Lotion.
- if you need to treat a premature or young baby. More lindane can go through the skin of babies and go to their brains where it can harm them.
- while you are breast-feeding. Lindane Lotion can get in your milk and be fed to your baby. Lindane Lotion on your skin can also go to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Lotion, pump your breast milk and throw away the milk for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk you stored from before you used Lindane Lotion.

Tell your doctor if you:

- used Lindane Lotion in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Lotion may cause seizures even if you never had them before.
- are pregnant. Lindane Lotion can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Lotion only if needed.

- have a sexual partner. Your partner should get checked and treated for scabies so they don't give them back to you. Don't share your Lindane Lotion with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Lotion. Especially, tell your doctor if you take medicines called sedatives (drugs to help you sleep).

How do I use Lindane Lotion?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Lotion on another person, wear special gloves made of nitrile, latex with neoprene, or sheet vinyl. **Do not use natural latex gloves because more lindane can go through that kind of glove. Wash your hands well when you are done.**
- Make sure your skin is clean and does not have any other lotion, cream, or oil on it. Oils can make Lindane Lotion go through your skin faster and may increase the risk of seizures.
- Wait for at least 1 hour after bathing or showering before you put Lindane Lotion on your skin. Wet or warm skin can make the Lindane Lotion go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Lotion well.
- Put Lindane Lotion under your fingernails, because the scabies really like to stay there. Trim your fingernails short. Use a toothbrush to get the Lindane Lotion under your fingernails. Wrap this toothbrush in paper and throw this toothbrush away. Do not use it in your mouth.
- Put a very thin layer of the Lindane Lotion on your skin from the neck down. You may have some Lindane Lotion left in the bottle.
- Do not cover over the Lindane Lotion on your skin with anything that does not breathe, like diapers with a plastic lining, plastic clothes, tight clothes, or blankets.
- Close the bottle with the leftover Lindane Lotion and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- Wash the Lindane Lotion off your skin after 8 to 12 hours. You must wash the Lindane Lotion off your body completely.

Use warm, but not hot water. Lindane Lotion will not kill any more scabies after 8 to 12 hours. After 8 to 12 hours, Lindane Lotion can cause serious health problems, such as seizures and death.

After you wash off the Lindane Lotion:

- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Lotion again. If you think you need to use it again, you must check with your doctor to find out when it is most safe.

You may still itch after you use Lindane Lotion. **This does not mean you need more Lindane Lotion.** Even after all the scabie bugs are dead, they can still make your skin itch for a few weeks. Lindane Lotion sometimes makes this itch even worse. Talk to your doctor about things you can do to soothe the itch.

What should I avoid while using Lindane Lotion?

- Do not get Lindane Lotion in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not let your skin touch other people's skin while you have Lindane Lotion on. Make sure your skin does not touch your baby or small child.
- If you are pregnant, do not use Lindane Lotion, or apply Lindane Lotion to others unless it is needed and you have talked to your doctor about using it. See the special glove advice below if you have to put Lindane Lotion on others.
- Do not use oils on your skin or hair just before or after using Lindane Lotion. Oils include skin lotions and moisturizers, and oil-based hair products and conditioners.
- Do not get Lindane Lotion on your hands if you are putting it on someone else. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.

What are the possible side effects of Lindane Lotion?

Lindane Lotion may cause serious side effects such as seizures (convulsions, fits) or death (See the section, “What is the most important information I should know about Lindane Lotion?”). Lindane Lotion can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Lotion are:

- Itching skin

- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Lotion. For more information, ask your doctor or pharmacist.

General Information about Lindane Lotion:

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Lotion for any condition for which it was not prescribed. Do not give Lindane Lotion to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Lotion and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Lotion. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Lotion that is written for health professionals.

What are the ingredients in Lindane Lotion?

Active Ingredient: Lindane.

Inactive Ingredients: 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylene glycol, propylparaben, purified water, stearic acid and trolamine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This medication is available only by a prescription from your doctor.

Product No.: 8546

Manufactured By:
Morton Grove Pharmaceuticals Inc.
Morton Grove, IL 60053

Distributed By:
Alliant Pharmaceuticals, Inc.
Alpharetta, GA 30004

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Medication Guide

LINDANE LOTION, USP 1%

Lindane (LIHN-dane) Lotion, USP 1%

You must read and follow all instructions before using Lindane Lotion. Read the information you get every time you or a family member get Lindane Lotion. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Lindane Lotion, ask your doctor or pharmacist.

What is the most important information I should know about Lindane Lotion?

Lindane Lotion is a poison if you do not use it the right way. Lindane Lotion goes through your skin and may affect your brain and nerves. Lindane Lotion can cause seizures, also called convulsions, "fits" or epilepsy.

- Seizures and death can happen in people who use Lindane Lotion too much or too often.
- Seizures can happen in some people even if they use Lindane Lotion exactly as directed.

If you or a family member has a seizure while using Lindane Lotion, get emergency help right away.

- Do not use Lindane Lotion unless:
  - You have scabies and were treated with another medicine that did not work for you, or
  - You cannot use other safer medicines to treat your scabies.
- Do not use Lindane Lotion more than 1 time to treat an attack of scabies. Do not use Lindane Lotion to treat a second attack of scabies that comes soon after the first episode. Using it more than 1 time can cause seizures and death. No one knows a safe time to reuse Lindane Lotion. Even if you still itch after using Lindane Lotion, do not use more or use it again. Scabies (bugs) can make your skin itch for a few weeks even after all of the bugs are dead.
- Do not use more Lindane Lotion than your doctor tells you.
- Do not keep Lindane Lotion on your skin for more than 8 to 12 hours.
- Do not put Lindane Lotion in your mouth because it is a poison if taken by mouth. If you get Lindane Lotion in your mouth or swallow Lindane Lotion, call your area Poison Control Center right away and get emergency help.

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Lindane Lotion is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds, use Lindane Lotion only if your doctor thinks it is really needed. People who weigh less than 110 pounds and the elderly have higher chances for side effects because more lindane may go through their skin.

Who should not use Lindane Lotion?

Do not use Lindane Lotion:

- if you do not have scabies. Lindane Lotion does not stop you from getting scabies. Lindane Lotion only kills the scabies you already have.
- if you have or have ever had seizures, also called convulsions, "fits" or epilepsy, especially if they have been hard to control.
- if you used Lindane Lotion in the past few months. You should see your doctor if you think you need another treatment.
- unless it is the only medicine you can use for scabies.
- if you had a bad reaction to Lindane Lotion before. **Do not use Lindane Lotion again.**
- if you have open sores or crusted (scabby) sores on your skin, or lots of broken skin.
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- if you are allergic to Lindane Lotion or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Lotion.
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Tell your doctor if you:

- used Lindane Lotion in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Lotion may cause seizures even if you never had them before.
- are pregnant. Lindane Lotion can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Lotion only if needed.

- have a sexual partner. Your partner should get checked and treated for scabies so they don't give them back to you. Don't share your Lindane Lotion with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Lotion. Especially, tell your doctor if you take medicines called sedatives (drugs to help you sleep).

How do I use Lindane Lotion?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Lotion on another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. **Do not use natural latex gloves because more lindane can go through that kind of glove. Wash your hands well when you are done.**
- Make sure your skin is clean and does not have any other lotion, cream, or oil on it. Oils can make Lindane Lotion go through your skin faster and may increase the risk of seizures.
- Wait for at least 1 hour after bathing or showering before you put Lindane Lotion on your skin. Wet or warm skin can make the Lindane Lotion go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Lotion well.
- Put Lindane Lotion under your fingernails, because the scabies really like to stay there. Trim your fingernails short. Use a toothbrush to get the Lindane Lotion under your fingernails. Wrap this toothbrush in paper and throw this toothbrush away. Do not use it in your mouth.
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- Do not cover over the Lindane Lotion on your skin with anything that does not breathe, like diapers with a plastic lining, plastic clothes, tight clothes, or blankets.
- Close the bottle with the leftover Lindane Lotion and throw it away in a trash can **out of the reach of children.**

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- Wash the Lindane Lotion off your skin after 8 to 12 hours. You must wash the Lindane Lotion off your body completely. Use warm, but not hot water. Lindane Lotion will not kill any more scabies after 8 to 12 hours. After 8 to 12 hours, Lindane Lotion can cause serious health problems, such as seizures and death.

After you wash off the Lindane Lotion:

- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
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What should I avoid while using Lindane Lotion?

- Do not get Lindane Lotion in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not let your skin touch other people's skin while you have Lindane Lotion on. Make sure your skin does not touch your baby or small child.
- If you are pregnant, do not use Lindane Lotion, or apply Lindane Lotion to others unless it is needed and you have talked to your doctor about using it. See the special glove advice below if you have to put Lindane Lotion on others.
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- Do not get Lindane Lotion on your hands if you are putting it on someone else. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.

What are the possible side effects of Lindane Lotion?

Lindane Lotion may cause serious side effects such as seizures (convulsions, fits) or death (See the section, "What is the most important information I should know about Lindane Lotion?"). Lindane Lotion can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Lotion are:

- Itching skin
- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Lotion. For more information, ask your doctor or pharmacist.

General Information about Lindane Lotion:

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Lotion for any condition for which it was not prescribed. Do not give Lindane Lotion to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Lotion and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Lotion. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Lotion that is written for health professionals.

What are the ingredients in Lindane Lotion?

Active Ingredient: Lindane.

Inactive Ingredients: 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylene glycol, propylparaben, purified water, stearic acid and trolamine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This medication is available only by a prescription from your doctor.

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Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

Distributed By:
Alliant Pharmaceuticals, Inc.
Alpharetta, GA 30004

28546A
ISS. 04-05

LINDANE SHAMPOO, USP 1%

Rx only

WARNINGS:

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE.)

Neurologic Toxicity

Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Contraindications

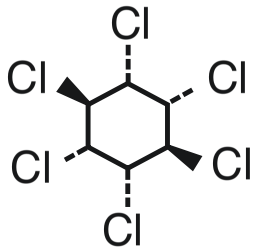
Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

Proper Use

Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo. (See DOSAGE AND ADMINISTRATION.)

DESCRIPTION

Lindane Shampoo, USP 1%, is an ectoparasiticide and ovicide effective against *Pediculosis humanis capitis* (head lice), *Pthirus pubis* (crab lice), and their ova. In addition to the active ingredient, lindane, it contains triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water to form a shampoo base. The pH may be adjusted with 10% hydrochloric acid solution and/or 10% sodium hydroxide solution. Lindane is the gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane having the following structural formula:



$C_6H_6Cl_6$ M.W. 290.83

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CLINICAL PHARMACOLOGY

Lindane exerts its parasiticidal action by being directly absorbed into the parasites and their ova. Feldmann and Maibach[1] reported approximately 10% absorption of a lindane acetone solution applied to the forearm of human subjects and left in place for 24 hours. This vehicle was different from the approved product and the percutaneous penetration of lindane is dependent on the vehicle. Therefore, the clinical significance of these observations is unknown. Dale, et al[2] reported a blood level of 290 ng/mL associated with convulsions following the accidental ingestion of a lindane-containing product. Ginsburg[3] found a mean peak blood level of 28 ng/mL 6 hours after total body application of Lindane Lotion to scabietic infants and children. The half-life in blood was determined to be 18 hours.

Data available in the literature suggest that lindane has a rapid distribution phase followed by a longer β-elimination phase.[1,2,3]

There are no clinical dose ranging studies for Lindane Shampoo.

INDICATIONS AND USAGE

Lindane Shampoo is indicated for the treatment of head lice (infestations of *Pediculosis humanis capitis*), crab lice (infestations of *Pthirus pubis*), and their ova only in patients who

1. cannot tolerate other approved therapies, or
2. have failed treatment with other approved therapies.

Lindane Shampoo should be used in the context of an overall lice management program that includes:

- Visual inspection to ensure that the patient is currently infested with live lice (empty egg casings or “nits” can remain on hair shaft long after true infestation).
- Manual removal of nits using a comb designed for this purpose and/or individual removal with tweezers followed by close examination of the hair and scalp.
- Evaluation and treatment of sexual contacts simultaneously. Sexual contacts should be prescribed Lindane Shampoo only if they either have failed to respond to adequate doses of other approved therapies or are intolerant of other approved therapies.
- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.

Caregivers applying this product to patients should wear gloves less permeable to Lindane such as nitrile, latex with neoprene or sheer vinyl, and thoroughly clean hands after application. Natural latex gloves should be avoided because they are more permeable to Lindane.

Lindane Shampoo does not prevent infestation or reinfestation and should not be used to ward off a possible infestation.

CONTRAINDICATIONS

Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane.

Lindane Shampoo is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.

Lindane Shampoo is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

WARNINGS (See boxed WARNINGS.)

Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions.

There have been cases of adverse events reported for Lindane Shampoo and Lindane Lotion in which a serious outcome (hospitalization, disability or death) has occurred.[4] In approximately 20% of these cases, the shampoo and lotion were reported to have been used according to the labeled directions. Of these cases, thirteen deaths were reported, many of which were remote from the time of actual Lindane use. Lindane toxicity, verified by autopsy was the cause of one infant's death, and was the cause of death reported for an adult in a successful suicide. The direct causes of death for the other cases were attributed to reasons other than lindane. Most of these adverse events occurred with Lindane Lotion.

Infants, children, the elderly, and individuals with other skin conditions and those who weigh < 110 lbs (50 kg) may be at a greater risk of serious neurotoxicity. (See Pediatric Use and Geriatric Use.) Animal studies have shown increased susceptibility to neurologic adverse events in younger animals. Children have a larger body surface area to volume ratio that may result in a proportionately larger systemic exposure.

Careful consideration should be given before prescribing Lindane Shampoo to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold. (See PRECAUTIONS: Drug Interactions.)

Patients should be instructed on the proper use of Lindane Shampoo, especially the amount to apply, how long to leave shampoo on, and the need to avoid retreatment. Patients should be informed that itching may occur after the successful killing of lice and

repeat treatment may not be necessary.

A Lindane Shampoo Medication Guide must be given to the patient each time Lindane Shampoo is dispensed, as required by law.

PRECAUTIONS

General: Care should be taken to avoid contact with the eyes. If such contact occurs, eyes should be immediately flushed with water. If irritation or sensitization occurs, the patient should be advised to consult a physician.

Information for Patients (and Caregivers):

- **This product can be poisonous if misused.**
- **Other important information is found in the Medication Guide, which by law, must be dispensed with Lindane Shampoo.**
- If putting Lindane Shampoo on another person, the person applying shampoo should wear less permeable gloves such as nitrile, latex with neoprene, or sheer vinyl, and thoroughly clean their hands after application. Natural latex should be avoided because it is more permeable to lindane.
- If the person applying Lindane Shampoo could be pregnant, contact with Lindane Shampoo should be avoided as much as possible.
- If the patient could be pregnant, other treatments may be preferable.
- Use Lindane Shampoo for lice only.
- The use of oil treatments, oil based hair dressings or conditioners immediately before and after applying Lindane Shampoo should be avoided. Oils can make the Lindane Shampoo go through the skin faster and possibly increase the risk of neurotoxicity (e.g., seizures).
- Information for Use
  - Shake Lindane Shampoo well.
  - Hair should be completely dry prior to application of Lindane Shampoo.
  - Use only enough Lindane Shampoo to lightly coat the hair and scalp.
  - Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Special attention should be given to the fine hairs along the neck and behind the ears.
  - After 4 minutes, add small quantities of water to hair until a good lather forms.
  - Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces.

- Towel briskly and then remove nits with nit comb or tweezers.
- There may be some Lindane Shampoo left in the bottle. Close the bottle with the leftover Lindane Shampoo and immediately throw away the bottle in a trash can out of the reach of children.
- Do not cover the hair with anything that does not breathe, like a shower cap or towel.
- Do not ingest. Keep away from mouth and eyes. If contact with eyes occurs, immediately flush eyes with water. Do not use if open wounds, cuts or sores are present, unless specifically directed by your physician.
- Wash all recently worn clothing, underwear and pajamas, hats, and used sheets, pillowcases, and towels in very hot water or dry-clean.
- Patients may still itch after using Lindane Shampoo. This does not mean the medicine did not work. Lindane Shampoo sometimes makes this itch even worse. Other medications can be used to soothe the itch. Do not use more Lindane Shampoo.
- If there are any questions or concerns about the condition or use of the Lindane Shampoo, contact your physician.

Drug Interactions: Oils may enhance absorption of lindane, therefore, patients and caregivers applying the shampoo to others should avoid using oil treatments, or oil-based hair dressings or conditioners immediately before and after applying Lindane Shampoo.

In addition, there are many drugs that may lower the seizure threshold, and Lindane Shampoo should be prescribed with caution in patients taking these medications. Drugs that may lower the seizure threshold include, but are not limited to the following:

- Antipsychotics
- Antidepressants
- Theophylline
- Cyclosporine, mycophenolate mofetil, tacrolimus capsules
- Penicillins, imipenem, quinolone antibiotics
- Chloroquine sulfate, pyrimethamine
- Isoniazid
- Meperidine
- Radiographic contrast agents
- Centrally active anticholinesterases
- Methocarbamol

Carcinogenesis, Mutagenesis, and Fertility: Although no studies have been conducted with Lindane Shampoo, numerous long-term feeding studies have been conducted in mice and rats to evaluate the carcinogenic potential of the technical grade of hexachlorocyclohexane as well as the alpha, beta, gamma (lindane) and delta isomers. Both oral and topical applications have been evaluated. Increased incidences of neoplasms were not clearly related to administration of lindane. The results of mutagenicity tests in bacteria do not indicate that lindane is mutagenic. Lindane did not cause sister chromatid exchange in an *in vivo* assay. The number of spermatids in the testes of rats 2 weeks after oral administration of a single dose of 30 mg/kg body weight (12 times the estimated human exposure for scabies on a body surface area comparison and assuming 50% rat oral bioavailability and 10% human bioavailability) was significantly reduced compared to the control rats.

Pregnancy: Pregnancy Category C. All pregnancies have a risk of birth defect, loss, or other adverse event regardless of drug exposure. Predictions of fetal risk from drug exposure rely heavily on animal data. However, animal studies may fail to predict effects in humans or may overstate such risks. Even if human data are available, the data may not be sufficient to determine whether there is an increased risk to the fetus, and individual reports of adverse outcomes in pregnancy in association with a drug may not reflect a causal relationship.

Lindane Shampoo should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Shampoo in pregnant women. There are no known maternal or fetal health risks described if lice are not treated, but risk of transmission of the lice to other household members is an additional consideration when deciding whether to use lice treatments. Lindane is lipophilic and may accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures during pregnancy to Lindane Lotion. The relationship of the maternal exposures to the fetal outcome is unknown.

Animal data suggest that lindane may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair covered areas is expected to be lower than that from Lindane Lotion that covers the entire body surface area.

Data: When rats received lindane in the diet from day 6 of gestation through day 10 of lactation, reduced pup survival, decreased pup weight and decreased weight gains during lactation, increased motor activity and decreased motor activity habituation were seen in pups at 5.6 mg/kg (2 times the estimated human exposure) but not at 1.2 mg/kg. An increased number of stillborn pups was seen at 8 mg/kg, and increased pup mortality was seen at 5.6 mg/kg. No gross abnormalities were seen in this study or in

a study in which rabbits received up to 20 mg/kg lindane by gavage on gestation day 6-18 (up to 10 times the human exposure on a body surface area comparison and assuming 50% rabbit oral bioavailability and 10% human bioavailability when lindane is applied to the entire body for the treatment of scabies).

Nursing Mothers: Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding if Lindane Shampoo is applied topically to the chest area. Nursing mothers who require treatment with Lindane Shampoo should be advised of the potential risks and be instructed not to use the product on the skin as would be done for treatment of scabies. They should also be counseled to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use.

Pediatric Use: Animal data demonstrated increased risk of adverse events in the young across species. Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver. Lindane Shampoo should be used with caution in patients who weigh less than approximately 110 lbs (50 kg) and especially in infants. Lindane Shampoo is indicated only for the treatment of lice; patients with scabies should use Lindane Lotion according to the labeled instructions.

Geriatric Use: There have been no studies of Lindane Shampoo in the elderly. There are four postmarketing reports of deaths in elderly patients treated with Lindane Lotion for the indication of scabies. Two patients died within 24 hours of Lindane Lotion application, and the third patient died 41 days after application of Lindane Lotion, having suffered a seizure on the day of death. A fourth patient died of an unreported cause of death on the same day that Lindane Lotion treatment for scabies was administered.

ADVERSE REACTIONS

Central nervous system stimulation ranging from dizziness to seizures, has been reported particularly with use of Lindane Lotion. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Shampoo was used according to directions. Irritant dermatitis from contact with this product has also been reported. (See WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION.)

Postmarketing Experience: The following adverse reactions reflect the additional postmarketing experience of Lindane Shampoo. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria. The relationship of

some of these events to lindane therapy is unknown.

OVERDOSAGE

Contact the closest Poison Control Center in the event of suspected overdosage with Lindane Shampoo.

If accidental ingestion occurs, prompt gastric lavage should be instituted. However, since oils enhance absorption, saline cathartics for intestinal evacuation should be given rather than oil laxatives. If central nervous system manifestations occur, they may be antagonized by the administration of pentobarbital, phenobarbital, or diazepam.

DOSAGE AND ADMINISTRATION

Most patients will require only 1 ounce of Lindane Shampoo. Based on the length and density of hair, some patients may require 2 ounces of Lindane Shampoo.

Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Special attention should be given to the fine hairs along the neck. After 4 minutes, add small quantities of water to hair until a good lather forms. Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces. Do not prescribe more than 2 ounces for larger adults. Do not retreat. (See boxed WARNINGS.)

Patients should be provided specific information on use of product. (See PRECAUTIONS: Information for Patients and Lindane Shampoo Medication Guide.)

A **Lindane Shampoo Medication Guide** must be given to the patient each time LINDANE Shampoo is dispensed as required by law. The Lindane Shampoo Medication Guide is an important part of the risk management program for the patient.

HOW SUPPLIED

Lindane Shampoo, USP 1% is supplied in patient-size 2 fl oz (60 mL) bottles.

SHAKE WELL BEFORE USING

Store at controlled room temperature, 15 °- 30 °C (59 °-86 °F) [see USP].

REFERENCES

1. Feldmann, R.J. and Maibach, H.I., *Toxicol. Applied. Pharmacol.*, 28:126, 1974.
2. Dale, W.E., Curly, A. and Cueto, C. *Life Sci* 5:47, 1966.
3. Ginsburg, C.M., et al., *J. Pediatr.* 91:6, 998-1000, 1977.
4. FDA AERS database search, January 2003

Rx Only

Product No.: 8547

Manufactured By: Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053

Distributed By: Alliant Pharmaceuticals, Inc. Alpharetta, GA 30004 A42-8547-60 REV. 06-05

PHARMACIST—PATIENT MEDICATION GUIDE PROVIDED BELOW

MEDICATION GUIDE
Lindane (LIHN-dane) Shampoo, USP 1%

You must read and follow all instructions before using Lindane Shampoo. Read the information you get every time you or a family member get Lindane Shampoo. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Lindane Shampoo, ask your doctor or pharmacist.

What is the most important information I should know about Lindane Shampoo?

Lindane Shampoo is a poison if you do not use it the right way. Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, "fits" or epilepsy.

- Seizures and death can happen in people who use Lindane Shampoo too much or too often.
- Seizures can happen in some people even if they use Lindane Shampoo exactly as directed.

If you or a family member has a seizure while using Lindane Shampoo, get emergency help right away.

- Do not use Lindane Shampoo unless
  - You have lice and another medicine did not work for you, or
  - You cannot use other, safer medicines to treat your lice
- Do not use Lindane Shampoo more than 1 time to treat an attack of lice. Do not use Lindane Shampoo to treat a second attack that comes soon after the first episode. No one knows a safe time to reuse Lindane Shampoo. Even if you still itch even after using Lindane Shampoo, do not use more or use it again. Lice (bugs) can make you itch for some time even after all of the bugs are dead.
- Do not use more Lindane Shampoo than your doctor tells you.
- Do not keep Lindane Shampoo on your hair for more than 4 minutes.

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- Do not put Lindane Shampoo in your mouth because it is a poison if taken by mouth. If you get Lindane Shampoo in your mouth or swallow Lindane Shampoo, call your area Poison Control Center right away and get emergency help.

What is Lindane Shampoo?

Lindane Shampoo is a medicine that is used to treat lice. It kills lice and their eggs. Lice are very small bugs that attach to the skin on your head or pubic (crotch) area and lay eggs called nits in your hair. Some people call crotch lice "crabs". Lice can cause severe itching. Lindane Shampoo gets into the lice and the nits and kills them. It also goes through your skin. Lindane Shampoo is used only after safer medicines have not made your lice go away. The only time Lindane Shampoo is used first is when someone cannot use safer medicines, which may include permethrin and crotamiton.

Lindane Shampoo is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds use Lindane Shampoo only if your doctor thinks it is really needed. People who weigh less than 110 pounds and the elderly have higher chances for side effects because more Lindane may go through their skin.

Who should not use Lindane Shampoo?

Do not use Lindane Shampoo:

- if you do not have lice. Lindane Shampoo does not stop you from getting lice. Lindane Shampoo only kills the lice you already have.
- if you have or have ever had seizures, also called convulsions, "fits" or epilepsy, especially if they have been hard to control.
- if you have used Lindane Shampoo in the past few months. You should see your doctor if you think that you need another treatment.
- unless it is the only medicine you can use for lice.
- if you had a bad reaction to Lindane Shampoo before. **Do not use Lindane Shampoo again.**
- if you have open sores or crusted (scabby) sores on the skin around your head and neck, or lots of broken skin.
- if you need to treat a premature or young baby. More of the applied Lindane can go through the skin of babies and go to their brains where it can harm them.
- if you have scabies. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Shampoo or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Shampoo.
- while you are breast-feeding. Lindane Shampoo can get in your milk and may be fed to your baby. Your baby may get

sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo.

Tell your doctor if you:

- used Lindane Shampoo in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Shampoo may cause seizures even if you never had them before.
- are pregnant. Lindane Shampoo can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Shampoo only if needed.
- have a sexual partner and your lice (crabs) are in your pubic (crotch) area. Your partner should get checked and treated for lice so they don't give them back to you. Don't share your Lindane Shampoo with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Shampoo. Especially tell your doctor if you take medicines called sedatives (drugs to help you sleep).

How do I use Lindane Shampoo?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Shampoo on another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. **Do not use natural latex gloves because more Lindane can go through that kind of glove.** Keep the gloves on until the Lindane Shampoo is washed out of your hair. **Wash your hands well when you are done.**
- Make sure your hair and skin on your head and neck do not have any other shampoo, cream, or oil on it. Oils can make the Lindane Shampoo go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Shampoo well.
- Make sure your hair is clean and dry before using Lindane Shampoo, but do not wash your hair within 1 hour before using Lindane Shampoo. Use regular shampoo without conditioner and dry your hair.

- Use just enough Lindane Shampoo on your dry hair to wet your hair and scalp. Do not add water to your hair at this time. Also, put Lindane Shampoo on the short hairs at the back of your neck.
- Keep Lindane Shampoo on your hair for 4 minutes. Use a watch or clock to time yourself.
- Do not wear a shower cap or any covering on your head while you wait for the 4 minutes to pass.
- Close the bottle with the leftover Lindane Shampoo and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- After 4 minutes has passed, soap up or lather the Lindane Shampoo. Use a small amount of warm water to do this. Hot water is not safe. Then wash the Lindane Shampoo off your head. Again, use warm, but not hot water. Do not leave any Lindane Shampoo on your head or hair. It will not kill more of the lice and may continue to go through your skin and cause serious problems, such as seizures.

After you wash off Lindane Shampoo:

- Dry your hair with a towel. Use a special comb called a nit comb or tweezers to remove the dead nits (lice eggs) from your hair. Someone else will probably have to do this for you.
- All recently worn clothing, underwear, pajamas, hats, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Shampoo again. If you think you need to use it again, you must check with your doctor to find out if and when it is most safe.

You may still itch after you have used Lindane Shampoo. This does not mean you need more Lindane Shampoo. Even after all the lice (bugs) are dead, they can still make your skin itch for a long time. Lindane Shampoo sometimes makes this itch even worse. Talk to your doctor about things you can do to soothe the itch.

What should I avoid while using Lindane Shampoo?

- Do not get Lindane Shampoo in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not get Lindane Shampoo on your hands. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.
- If you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special glove advice above if you have to put Lindane Shampoo on others.
- Do not use oils on your skin or hair, just before or after using Lindane Shampoo. Oils include oil-based hair products

and conditioners.

What are the possible side effects of Lindane Shampoo?

Lindane Shampoo may cause serious side effects such as seizures (convulsions, fits) or death (See the section, "What is the most important information I should know about Lindane Shampoo?"). Lindane Shampoo can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Shampoo are:

- Itching skin
- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Shampoo. For more information, ask your doctor or pharmacist.

General Information about Lindane Shampoo:

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Shampoo for any condition for which it was not prescribed. Do not give Lindane Shampoo to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Shampoo and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Shampoo. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Shampoo that is written for health professionals.

What are the ingredients in Lindane Shampoo?

Active Ingredient: Lindane.

Inactive Ingredients: triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Lindane is only available by a prescription from your doctor.

Product No.: 8547
A42-8547-60 REV. 06-05

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

Distributed By:
Alliant Pharmaceuticals, Inc.
Alpharetta, GA 30004

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Medication Guide

LINDANE SHAMPOO, USP 1%

Lindane (LIHN-dane) Shampoo, USP 1%

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- Seizures and death can happen in people who use Lindane Shampoo too much or too often.
- Seizures can happen in some people even if they use Lindane Shampoo exactly as directed.

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- if you need to treat a premature or young baby. More of the applied Lindane can go through the skin of babies and go to their brains where it can harm them.
- if you have scabies. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Shampoo or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Shampoo.
- while you are breast-feeding. Lindane Shampoo can get in your milk and may be fed to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo.

Tell your doctor if you:

- used Lindane Shampoo in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Shampoo may cause seizures even if you never had them before.

- are pregnant. Lindane Shampoo can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Shampoo only if needed.
- have a sexual partner and your lice (crabs) are in your pubic (crotch) area. Your partner should get checked and treated for lice so they don't give them back to you. Don't share your Lindane Shampoo with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Shampoo. Especially tell your doctor if you take medicines called sedatives (drugs to help you sleep).

How do I use Lindane Shampoo?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Shampoo on another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. **Do not use natural latex gloves because more Lindane can go through that kind of glove.** Keep the gloves on until the Lindane Shampoo is washed out of your hair. **Wash your hands well when you are done.**
- Make sure your hair and skin on your head and neck do not have any other shampoo, cream, or oil on it. Oils can make the Lindane Shampoo go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Shampoo well.
- Make sure your hair is clean and dry before using Lindane Shampoo, but do not wash your hair within 1 hour before using Lindane Shampoo. Use regular shampoo without conditioner and dry your hair.
- Use just enough Lindane Shampoo on your dry hair to wet your hair and scalp. Do not add water to your hair at this time. Also, put Lindane Shampoo on the short hairs at the back of your neck.
- Keep Lindane Shampoo on your hair for 4 minutes. Use a watch or clock to time yourself.
- Do not wear a shower cap or any covering on your head while you wait for the 4 minutes to pass.
- Close the bottle with the leftover Lindane Shampoo and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- After 4 minutes has passed, soap up or lather the Lindane Shampoo. Use a small amount of warm water to do this. Hot water is not safe. Then wash the Lindane Shampoo off your head. Again, use warm, but not hot water. Do not leave any Lindane Shampoo on your head or hair. It will not kill more of the lice and may continue to go through your skin and cause serious problems, such as seizures.

After you wash off Lindane Shampoo:

- Dry your hair with a towel. Use a special comb called a nit comb or tweezers to remove the dead nits (lice eggs) from your hair. Someone else will probably have to do this for you.
- All recently worn clothing, underwear, pajamas, hats, used sheets, pillow-cases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Shampoo again. If you think you need to use it again you must check with your doctor to find out if and when it is most safe.

You may still itch after you have used Lindane Shampoo. **This does not mean you need more Lindane Shampoo.** Even after all the lice (bugs) are dead, they can still make your skin itch for a long time. Lindane Shampoo sometimes makes this itch even worse. Talk to your doctor about things you can do to soothe the itch.

What should I avoid while using Lindane Shampoo?

- Do not get Lindane Shampoo in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not get Lindane Shampoo on your hands. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.
- If you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special glove advice above if you have to put Lindane Shampoo on others.
- Do not use oils on your skin or hair, just before or after using Lindane Shampoo. Oils include oil-based hair products and conditioners.

What are the possible side effects of Lindane Shampoo?

Lindane Shampoo may cause serious side effects such as seizures (convulsions, fits) or death (See the section, "What is the most important information I should know about Lindane Shampoo?"). Lindane Shampoo can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Shampoo are:

- Itching skin
- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Shampoo. For more information, ask your doctor or pharmacist.

General Information about Lindane Shampoo:

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Shampoo for any condition for which it was not prescribed. Do not give Lindane Shampoo to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Shampoo and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Shampoo. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Shampoo that is written for health professionals.

What are the ingredients in Lindane Shampoo?

Active Ingredient: Lindane.

Inactive Ingredients: triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Lindane is only available by a prescription from your doctor.

Product No.: 8547

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

Distributed By:
Alliant Pharmaceuticals, Inc.
Alpharetta, GA 30004

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Information DOWNLOADS ON LINDANE

Lindane lotion prescription labeling
Lindane shampoo prescription labeling
Lindane lotion medication guide
Lindane shampoo medication guide
U.S. Food and Drug Administration's (FDA) Response to Citizen's Petition, 1997
U.S. Centers for Disease Control and Prevention (CDC) 2006 Sexually Transmitted Disease Treatment Guidelines
U.S. Food and Drug Administration (FDA) Assessment Memorandum on Lindane, posted 2003
U.S. Environmental Protection Agency (EPA) Revised Assessment of Risk From Use of Lindane for Treatment of Lice and Scabies, July 2002
U.S. EPA Response to Comments on the 2002 Lindane RED, July 2006
U.S. EPA Evaluation of Lindane Carcinogenic Potential, 2001
World Health Organization Background Document on Lindane for Drinking-Water Quality Guidelines. 2004.

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Please See Important Safety Information on Lindane

Important SAFETY INFORMATION

When used as directed, lindane medications are relatively safe and effective. The most commonly reported side effects include itching skin, burning skin, dry skin, and rash. Other reported adverse events include: dizziness, headache, pain, paresthesia (tingling), hives, and alopecia (hair loss). However, the relationship of some of these effects to lindane therapy is unclear.

Serious adverse events with lindane medications, such as seizures and death, are rare, and have almost always resulted from product misuse (e.g., swallowing large quantities, prolonged or repeated application). Lindane medications are now limited to single-use 2 oz. bottles to minimize this risk. Please see Boxed Warnings below.

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Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Lindane lotion USP, 1%
Rx Only

WARNINGS:

Lindane lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies

Neurologic Toxicity

Seizures and deaths have been reported following lindane lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane lotion should be used with caution in infants, children, the elderly, and individuals with other skin conditions (e.g, atopic dermatitis, psoriasis) and in those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity

Contraindications

Lindane lotion is contraindicated in premature infants and individuals with known uncontrolled seizure disorders

Proper Use

Instruct patients on the proper use of lindane lotion, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of scabies and is not necessarily an indication for re-treatment with lindane lotion

Lindane shampoo USP, 1%
Rx Only

WARNINGS:

Lindane shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice

Neurologic Toxicity

Seizures and deaths have been reported following lindane shampoo use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane shampoo should be used with caution in infants, children, the elderly, and individuals with other skin conditions, and in those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity

Contraindications

Lindane shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders

Proper Use

Instruct patients on the proper use of lindane shampoo, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for re-treatment with lindane shampoo

Commitment to Public Health and Safety | Lindane Prescribing Information | FDA Information on Lindane

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

The Need for Second-line Medications like Lindane

Scabies and lice infestations remain common public health problems, despite available treatments. The inherent limitations of first-line medications and the unpredictable and increased incidence of treatment-resistant forms of scabies and lice necessitate the need for a range of treatment alternatives. Second-line therapies, more specifically, provide a valuable "last resort" for patients who have nowhere else to turn.

The Food and Drug Administration (FDA) has repeatedly and consistently maintained its position that lindane medications provide healthcare benefits that outweigh potential risks when used appropriately.[1] This position is based on extensive lindane reviews by medical and scientific experts and more than 50 years of clinical experience with lindane medications in healthcare.

Lindane lotion and lindane shampoo are approved for the second-line treatment of scabies and lice, meaning they are only prescribed for patients who have failed or cannot tolerate first-line medications[2,3]

Scabies and lice continue to impact public health

Scabies and lice are highly-contagious parasitic infestations of the skin that carry significant health risks if left untreated or treated unsuccessfully. (See Understanding Scabies and Lice)

Scabies and lice remain an ongoing challenge:

Worldwide, there are hundreds of millions of people infested with scabies and lice, reaching epidemic proportions in some areas and settings[4–6]
Scabies and lice have medical, social, and economic consequences that are estimated to cost hundreds of millions of dollars each year[7]

Limitations of First-Line Scabies and Lice Treatments

No treatment for scabies or lice is 100% effective[6]
Some patients cannot tolerate first-line medications due to allergic reactions or other adverse side effects[6]
Resistance of scabies and lice to approved medications is on the rise globally,

underscoring the need for multiple treatment options[4,5]

Currently available treatments for scabies and lice have significant limitations. Reducing the number of therapeutic options would be a disservice to patients who have limited options.

Please See Important Safety Information on Lindane

References:

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm.
2. Lindane lotion, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf.
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Treatment Options for Scabies and Lice

Topical medications, including prescription and over-the-counter remedies that are applied to the skin, are considered the mainstay of scabies and lice treatment. Unfortunately, none are 100% effective and some patients are intolerant of some of these medications because of allergies or adverse side effects. Moreover, treatment-resistant forms of scabies and lice have increased in recent years, further compromising the effectiveness of available medications. Manual removal of head lice and their nits with special combs is appropriate in select situations, but is labor intensive and not a preferred method.[1,2] As such, a range of first- and second-line treatment options is necessary for effective disease control and individualized patient care.

Points of View on Lindane:
FOOD AND DRUG ADMINISTRATION
ENVIRONMENTAL PROTECTION AGENCY
CENTERS FOR DISEASE CONTROL AND PREVENTION
MEDICAL & SCIENTIFIC OPINIONS

FDA-approved therapies for scabies are relatively limited

Medications that are currently approved by the Food and Drug Administration (FDA) for the topical treatment of scabies include:

Permethrin
Crotamiton
Lindane

An oral medication called ivermectin is also used for the management of scabies, but is not FDA-approved for this indication.[3] Additional information, including links to respective product labels, can be found in the table below.

Healthcare providers have few effective treatment options for managing scabies.

Medications Used To Treat Scabies

Medication (brand name)	Availability	CDC Position*	FDA Position
Permethrin 5% cream[4,5] (Elimite®, Acticin®)	Prescription only	Recommended regimen	Approved first line
Crotamiton 10% cream or lotion[6]	Prescription only	None	Approved first line

(Eurax®)			
Lindane 1% lotion[7] (generic only)	Prescription only	Alternative regimen	Approved second line†
Ivermectin oral tablets[8] (Stromectol®)	Prescription only	Recommended regimen—off-label use	Not approved for scabies

* As listed in 2006 Centers for Disease Control and Prevention's (CDC's) Sexually Transmitted Disease Treatment Guidelines.[9]
†Lindane is indicated for patients who have failed or cannot tolerate first-line medications.

Treatment failure with scabies medications occurs for many reasons:[10]

Resistance (demonstrated for all scabicides)
Improper application (e.g., only applied to selected areas)
Inadequate application (e.g., dilution, lack of compliance with regimen)
Reinfestation (e.g., failure to treat close social contacts or launder clothes/bedding)

Lice pose an ongoing treatment challenge

Lice infestation remains a significant public health problem in the U.S. despite the available treatments. Medications commonly used to treat lice include:

Pyrethrin
Permethrin
Lindane
Malathion

An oral medication called ivermectin is also used to treat lice but is not FDA approved for this indication.[8,11] Additional information, including links to respective product information, can be found in the table below.

Medications Used to Treat Head Lice and Pubic (crab) Lice

Medication (brand name)	Availability	CDC position—pubic lice only*	FDA position
Pyrethrins [0.33%] with piperonyl butoxide [4%][12] (Rid®)	Over-the-counter	Recommended regimen	Conforms to FDA over-the-counter drug monograph 21CFR 358.610
Permethrin 1% crème rinse[13] (Nix®)	Over-the-counter	Recommended regimen	Approved for first-line treatment of head lice only
Malathion 0.5%[14] (Ovide®)	Prescription only	Alternative regimen	Approved for first-line treatment of head lice only
Lindane 1% shampoo[15]	Prescription only	Second-line regimen	Approved for second-line† treatment of both head lice

(generic only)			and pubic (crab) lice
Ivermectin oral tablets[8] (Stromectol®)	Prescription only	Alternative regimen—off-label use	Not approved for lice

* As listed in 2006 Centers for Disease Control and Prevention's (CDC's) Sexually Transmitted Disease Treatment Guidelines.[9]

†Lindane is indicated for patients who have failed or cannot tolerate first-line medications.

Treatment failure with lice medications can occur for many reasons:[16]

Resistance (a concern with all available lice medications)
Poor compliance with treatment and medication regimens
Application to wet hair (i.e., dilutes medication and causes lice to shut down their breathing, further limiting their exposure to medication)
Reinfestation (e.g., re-exposure to lice or failure to treat personal social contacts)

Manual removal (â€œwet combingâ€) of nits is not a preferred method for treating lice

Manual removal is relatively labor intensive and involves the combing of wet hair ("wet combing") with a special comb for 15 to 30 minutes or more every 3 to 4 days for several weeks[17] (See: Fact Checker)

Moreover, evidence for the effectiveness of wet combing in controlling lice infestations is generally lacking[18]

The CDC and The American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over wet combing for the treatment of head lice[1,2]

Nonetheless, wet combing is an appropriate alternative when the use of medications is not appropriate (e.g., lindane should be used with caution in infants, children, the elderly, pregnant or lactating women, individuals with other skin conditions and in those who weigh <110 lbs.)

Please See Important Safety Information on Lindane

References:

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6. Eurax® (crotamiton cream and lotion) prescribing information. Available at: http://www.fda.gov/medwatch/SAFETY/2003/03Jun_PI/Eurax_PI.pdf.
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http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf.
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Lindane Product ADVANCEMENTS

Packaging · Prescription Product Labeling · Patient Education · Ongoing Research Investments

In recent years, a number of important changes to product packaging and prescription labeling have been made for lindane lotion and lindane shampoo in the U.S. market. Single-use containers and patient-friendly medication guides, in particular, have dramatically reduced the potential risk of serious adverse effects. The detailed prescribing information written for healthcare professionals, who prescribe lindane, has also been repeatedly updated for safety in collaboration with the Food and Drug Administration (FDA). (See Lindane Regulatory History) Moreover, ongoing investments in research and development have been designed to further advance the benefit-safety balance of lindane medications for the future. (See MGP Commitment)

Please See Important Safety Information on Lindane

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Commitment to Public Health and Safety | Lindane Prescribing Information | FDA Information on Lindane

0043

Lindane Product ADVANCEMENTS

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Prescription Packaging of Lindane

Both the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) agree that lindane medications are safe when used properly and that the majority of serious adverse events have resulted from product misuse (e.g., swallowing large quantities, excess application).[1,2] To minimize this risk and enhance product safety, lindane lotions and shampoos manufactured in the U.S. have been restricted to single-use, 2 oz. bottle packaging since 2003. Now, patients filling their lindane prescriptions receive just enough medication for a single treatment.[1]

Single-use 2 oz. packaging dramatically minimizes risk for misuse of lindane medications

Minimizes risk of excess application or reapplication of lindane
Minimizes risk of accidental or intentional oral ingestion of large quantities of lindane
Minimizes risk of use of leftover medication by persons other than the patient for whom lindane was prescribed (including others who may not actually be infected with scabies or lice)

0044

Lindane products	U.S.[3–5]	Canada[6]
Regulatory status	Prescription only	O.T.C.*, no prescription required
Packaging	2 oz., single-use bottle only	Up to 17 oz. bottle; enough lindane for 8 or more treatments

* O.T.C.=over-the-counter medication

Non-U.S. lindane packaging increases misuse potential

The availability of U.S.-manufactured lindane medications eliminates the need for patients with no other treatment options to turn to foreign suppliers, through websites or alternative channels, for less-regulated lindane products, where the risk for misuse and serious side effects is much greater.

> For example, the large, 17 oz. bottle of lindane sold in Canada makes it easier for less-informed patients and caregivers to misuse lindane, and increases the risk of serious adverse events from accidental or intentional ingestion of large amounts of lindane Moreover, lindane is available without a prescription from Canadian sources and is easily purchased by patients who are not required to see a healthcare provider for proper diagnosis and counseling
> The FDA has recently warned Canadian drug importers about consistent misrepresentation of the safety of foreign drug products and failure to include important patient safety information[7]

Keeping lindane on the market in the U.S. as a prescription therapy regulated by the FDA

protects the American public from the potential dangers discussed above.

Please See Important Safety Information on Lindane

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Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Prescription Lindane Labeling

The professional product labeling for lindane medications (also referred to as "full prescribing information") provides physicians and other healthcare providers with important information on the benefits, risks, and appropriate use of these lindane prescription therapies. Over the past three decades, the prescription labeling for lindane lotion and lindane shampoo has been updated for safety as new information has become available and reviewed by the Food and Drug Administration (FDA). (See Lindane Regulatory History) These updates, implemented by the U.S. manufacturer, help to maximize the safety of lindane medications in healthcare practice.

Recent changes in lindane prescription labeling improve the benefit-safety balance of lindane medications

In 2003, a boxed warning was added to lindane professional labeling to raise awareness among healthcare professionals of the potential risks for neurologic toxicity and proper use of lindane medications for the treatment of scabies and lice, including:[1]

Second-line use, for patients who have failed or who cannot tolerate approved first-line medications

Risk of neurologic toxicity, particularly with product misuse, and risks in infants, children, the elderly, individuals with other skin conditions, and patients weighing <110 lbs. (label suggests using lindane only with caution in these groups of patients) (See Adverse Events)

Contraindications in premature infants and persons with seizure history (label suggests never using lindane in these patients)

Proper use instructions, including how much lindane medication should be applied and how long it should be left on

The exact language in the current boxed warning for lindane lotion is shown below. Similar language is also contained in the boxed warning for lindane shampoo.[2,3]

> WARNINGS:
>
> Lindane lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies (See INDICATIONS AND USAGE.)

0047

Neurologic Toxicity

Seizures and deaths have been reported following lindane lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane lotion should be used with caution in infants, children, the elderly, and individuals with other skin conditions (e.g., atopic dermatitis, psoriasis) and in those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity

Contraindications

Lindane lotion use is contraindicated in premature infants and individuals with known uncontrolled seizure disorders

Proper Use

Instruct patients on the proper use of lindane lotion, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of scabies and is not necessarily an indication for re-treatment with lindane lotion (See DOSAGE AND ADMINISTRATION.)

Professional labeling of U.S. lindane products promotes safety

Lindane products	U.S.[2–4]	Canada[5]
Regulatory status	Prescription only	O.T.C.* , no prescription required
Professional product labeling	Reviewed and updated in close collaboration with the FDA; provides detailed scientific information and clinical guidance specifically for healthcare professionals	Due to O.T.C.* status, no professional labeling is required; package insert contains only information for patients, who may be unaware of the importance of consulting with a physician, nurse, or pharmacist

* O.T.C.=over-the-counter medication

Please See Important Safety Information on Lindane

References:

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm.
2. Lindane lotion, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf.
3. Lindane shampoo, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf.
4. U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER) Report to the Nation: 2003. Available at: http://www.fda.gov/cder/reports/rtn/2003/rtn2003-3.htm.
5. Lindane Canadian package insert: Lindane Shampoo and Lotion. Pharmascience, Inc., Montréal, Canada.

Commitment to Public Health and Safety | Lindane Prescribing Information | FDA Information on Lindane

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Lindane Patient Education

Appropriate use of lindane medications by patients and caregivers is an important aspect of their safety and effectiveness. In 2003, the Food and Drug Administration (FDA), in collaboration with the U.S. manufacturer, addressed this issue with the creation of patient-friendly medication guides for both lindane lotion and lindane shampoo. These guides are now required by law to be dispensed by pharmacists with every new lindane prescription.[1]

Lindane medication guides are designed to enhance lindane safety: [2,3]

Written in plain English, the medication guides help physicians and pharmacists to educate patients and caregivers on potential risks, proper use, and contraindications
The medication guides are integrated into the newer single-use packaging of lindane lotion and shampoo to ensure they are dispensed with each prescription

Well-informed patients are less likely to misuse medications like lindane

Lindane products	U.S.[2–6]	Canada[7]
Regulatory status	Prescription only	O.T.C.*, no prescription required
Patient-friendly medication guide	Packaged with each bottle and dispensed by pharmacist with each prescription—required by law	None

* O.T.C.=over-the-counter medication

click to enlarge

Lindane lotion and shampoo packaging ensures that the medication guide stays together with the bottle and is easily accessed by pharmacists, patients, and caregivers

Critical information covered in Medication Guides for lindane lotion and shampoo:[2,3]

What is lindane lotion/shampoo?
Who should not use lindane lotion/shampoo?
How do I use lindane lotion/shampoo?
- Before you put it on
- When you put it on
- When you are supposed to wash it off
- After you wash it off

What should I avoid while using lindane lotion/shampoo?

0050

What are the ingredients in lindane lotion/shampoo?

Please See Important Safety Information on Lindane

References:

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm.
2. Medication Guide Lindane Lotion USP, 1%. Updated March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneLotionGuide.htm.
3. Medication Guide Lindane Shampoo USP, 1%. Updated March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneShampooGuide.htm.
4. Lindane lotion, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf.
5. Lindane shampoo, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf.
6. U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER) Report to the Nation: 2003. Available at: http://www.fda.gov/cder/reports/rtn/2003/rtn2003-3.htm.
7. Lindane Canadian package insert: Lindane Shampoo and Lotion. Pharmascience, Inc., Montréal, Canada.

Commitment to Public Health and Safety | Lindane Prescribing Information | FDA Information on Lindane

Lindane Product ADVANCEMENTS

Information DOWNLOADS

Points of View on Lindane:

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Ongoing Lindane Research Investments

As a U.S. manufacturer of lindane medications, Morton Grove Pharmaceuticals, Inc. (MGP) recognizes the public health need to preserve lindane as a second-line therapy for the treatment of scabies and lice. Given that the majority of lindane safety issues relate to the potential for misuse, MGP has taken important measures to minimize this risk—and continues to do so.

Working in close collaboration with regulatory experts, MGP has taken the lead in developing and implementing a lindane clinical research program. This ongoing investment is designed to further enhance the benefit-safety balance of lindane medications.

The current lindane research program has multiple goals[1]

Evaluate safety of lindane medications
Evaluate efficacy of lindane medications
Evaluate safe and effective dose ranges for different patient types

Advancing lindane safety remains a priority

MGP has played an integral role in improving the safety of lindane medications for patients in the U.S. The company is proud of its work with regulatory experts at the Food and Drug Administration (FDA), and continues to look for new ways to enhance the safety and clinical utility of lindane medications through research and development efforts.

Lindane safety advancements implemented by MGP[2–7]

Single-use packaging: *Modified from the original 16 oz. bottle to small, single-use, 2 oz. bottles of lindane lotion and lindane shampoo*

Boxed warnings: *Updated lindane label for healthcare professionals, highlighting important risks (including neurologic toxicities) and patient selection criteria*

Patient-friendly lindane medication guide: *Packaged with each bottle and required by law to be dispensed by pharmacists with each lindane prescription to educate patients and caregivers on risks and appropriate use*

Please See Important Safety Information on Lindane

References:

1. Murphy MD. (Director, FDA Office of Pediatric Drug Development). "Re: ANDA 88-190, ANDA 88-191." Correspondence to Morton Grove Pharmaceuticals. September 30, 2003.
2. Lindane lotion, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf.
3. Lindane shampoo, USP, 1% prescribing information. Updated March 28, 2003. Available at: http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf.
4. Medication Guide Lindane Lotion USP, 1%. Updated March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneLotionGuide.htm.
5. Medication Guide Lindane Shampoo USP, 1%. Updated March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneShampooGuide.htm.
6. U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER) Report to the Nation: 2003. Available at: http://www.fda.gov/cder/reports/rtn/2003/rtn2003-3.htm.
7. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

OPPOSITION TO MORTON GROVE PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S COUNTERCLAIM

APPENDIX OF UNPUBLISHED CASES

App. 1 *Republic Tobacco v. North Atl. Trading Co.*, No. 98 C 4011, 1999 WL 261712 (N.D. Ill. Apr. 9, 1999)

App. 2 *Health Care Compare Corp. v. United Payors & United Providers, Inc.*, No. 96 C 2518, 1998 WL 122900 (N.D. Ill. Mar. 13, 1998)

App. 3 *Healthport Corp. v. Tanita Corp. of Am.*, No. 06-419-PK, 2008 WL 2224398 (D. Or. May 23, 2008)

App. 4 *Midwest Canvas Corp. v. Commonwealth Canvas, Inc.*, No. 07 C 0085, 2008 WL 162757 (N.D. Ill. Jan. 16, 2008)

App. 5 *Patient Transfer Sys., Inc. v. Patient Handling Solutions, Inc.*, No. CIV.A. 97-1568, 2001 WL 936641 (E.D. Pa. Aug. 16, 2001)

App. 6 *MasterCard Int'l, Inc. v. Nader 2000 Primary Comm., Inc.*, No. 00 Civ. 6068, 2004 WL 434404 (S.D.N.Y. Mar. 8, 2004)

App. 7 *Eazypower Corp. v. Alden Corp.*, No. 03 C 3164, 2003 WL 22859492 (N.D. Ill. Dec. 2, 2003)

App. 8 *McDonagh v. Bergan*, No. 03 C 1465, 2003 WL 21798735 (N.D. Ill. July 25, 2003)

App. 9 *Papa John's Int'l, Inc. v. Rezko*, No. 04 C 3131, 2006 WL 566468 (N.D. Ill. Mar. 3, 2006)

APPENDIX 1

HRepublic Tobacco, L.P. v. North Atlantic Trading Co.
N.D.Ill.,1999.

United States District Court, N.D. Illinois, Eastern Division.
REPUBLIC TOBACCO, L.P., Plaintiff,
v.
NORTH ATLANTIC TRADING COMPANY et al., Defendants.
No. 98 C 4011.

April 9, 1999.

MEMORANDUM OPINION

GRADY, District J.
***1** Before the court are two motions: defendants' motion to dismiss Counts I, IV, V, VII, VIII, IX, and X of the amended complaint and plaintiff's motion to strike defendants' counterclaim. For the reasons stated in this opinion, defendants' motion to dismiss is granted in part and denied in part. Plaintiff's motion to strike, more appropriately characterized as a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, is granted.

BACKGROUND

Plaintiff Republic Tobacco, L.P. ("Republic") is a Delaware limited partnership with its principal place of business in Chicago, Illinois. Republic imports and sells tobacco, roll-your-own ("RYO") cigarette papers, and other tobacco-related products. Defendant North Atlantic Trading Company, Inc. ("NATC"), Republic's direct competitor in the tobacco and tobacco-related products market, is a Delaware corporation headquartered in New York. Defendants North Atlantic Operating Company, Inc. ("NAOC") and National Tobacco Company, L.P. ("National") are wholly-owned subsidiaries of NATC. NAOC imports RYO cigarette papers and other tobacco-related products sold under the "ZIG-ZAG" brand name. National distributes and sells ZIG-ZAG cigarette papers, Beech-Nut loose leaf chewing tobacco, and other tobacco-related products. We will refer to all defendants collectively as "North Atlantic" where appropriate. The following allegations are taken from Republic's amended complaint.

Incentive Programs

Republic and North Atlantic market their RYO cigarette paper primarily through distributors and wholesalers, who resell the products to outlets such as convenience, drug, and variety stores and gas station/mini-marts. As part of its marketing strategy, Republic offers three programs to these customers as incentives to stock, sell, (and promote, in the case of distributors) Republic's products. Customers joining these incentive programs can receive rebates, free products, and free travel in exchange for stocking or promoting specified amounts of certain Republic RYO cigarette paper brands and meeting certain sales goals.[FN1]Amended Complaint, Exs. A-D (sample incentive program agreements).

> FN1. The Republic Value-Added Rebate Incentive Program provides incentives to distributors for stocking, promoting, and selling Republic products to their retail accounts. Amended Complaint, ¶ 12. The Republic Convenience Store Distribution Incentive Program provides incentives to convenience stores for stocking and selling Republic products. *Id.* ¶ 13.The Republic Travel Plus Program, open to both distributors and convenience stores, offers "points" to be used toward trips, such as cruises. *Id.* ¶ 14 & Exs. C, D.

Display Boxes

North Atlantic and its predecessors sometimes sold their RYO cigarette papers in limited promotional runs, packaged in a plastic display box.[FN2]Customers received ownership of the display box in return for buying the products inside. Some of Republic's customers wanted to use these boxes to display and sell Republic's RYO cigarette papers, so Republic obtained unused boxes from third-party distributors. Republic then re-labeled the boxes with its own labels, restocked the boxes with its products, and

made them available to the customers who had requested them.[FN3]

FN2. Most of the display boxes are off-white; some are colored.*Id* .¶ 17.

FN3. Republic also alleges that its sister company, Adams Apple Distributing Company, purchased some of the display boxes directly from U.S. Tobacco, without any restrictions on the use of the boxes. At the time, U.S. Tobacco was the national importer and distributor of ZIG-ZAG cigarette papers; Jack Africk, who is now president of North Atlantic, was U.S. Tobacco's Vice-Chairman and Executive Vice President. *Id.* ¶ 19.

Disparaging Remarks

Republic alleges that North Atlantic engaged in an unlawful "pattern of anticompetitive conduct" by making disparaging remarks to Republic's customers regarding Republic's incentive programs and display boxes. Republic claims that North Atlantic contacted Republic's customers, both orally and in writing, and falsely told those customers that Republic's incentive programs violated federal and state antitrust and unfair competition laws. Republic claims that "North Atlantic's statements were designed to interfere with Republic's customer relationships by causing customers to be concerned about the legality of the programs and to believe that Republic would be unable to honor its obligations under the programs ."*Id.* ¶ 16.

***2** Moreover, Republic contends that North Atlantic contacted many of Republic's customers and falsely told those customers that Republic's refurbishment of the display boxes violated patent and trademark laws. Republic claims that North Atlantic threatened those customers by stating that the customers might be sued for continuing to use the display boxes. Republic also alleges that North Atlantic threatened to sue display box distributors if the distributors sold any display boxes to Republic in the future, even those distributors who had never sold display boxes to Republic in the first place.*Id.* ¶ 20.

Republic alleges that North Atlantic made unlawful disparaging remarks on several occasions. First, John Czerewko, North Atlantic's director of sales for the Midwest, sent a letter in late January 1998 to Clark Refining and Marketing Company ("Clark"), which sells Republic's products to customers of its gas station/convenience stores. *Id.* ¶¶ 22-23.The letter reads:

Recently, another Chain was positioned for exclusivity and a modified, defaced Zig Zag [display box] was used. We own the patent-trademark which has been violated. Our Attorneys initiated legal action regarding this and had to include the Chain [that had used the display box] in Trademark-Patent violation.

Id., Ex. E ("Czerewko Letter"). Republic contends that these statements were false because North Atlantic held no patent or trademark rights in the boxes and had not initiated litigation against anyone in connection with the display boxes. Republic also asserts that the Czerewko letter falsely hints that Republic's incentive programs are illegal by referring to the programs as "Smoke & Mirrors" and warning Clark to "[b]e aware of the Robinson-Patman Act."[FN4]

FN4. The Robinson-Patman Act, 15 U.S.C. § 13(a)-(f), prohibits certain price discrimination by a seller among its customers.

Republic alleges that Clark forwarded the Czerewko letter to Clark's supplier, Eby-Brown, which buys products directly from Republic, and that Eby-Brown discontinued its participation in Republic's incentive programs after receiving the letter. Eby-Brown sent a memorandum to Republic in late May 1998, which stated that North Atlantic had notified Eby-Brown that it intended to take legal action to enforce its patents in the display boxes.[FN5]*Id.*, Ex. F. Republic alleges that Eby-Brown discussed the memorandum with Clark and that Clark subsequently discontinued its participation in Republic's incentive programs as well.[FN6]

FN5. Republic claims that North Atlantic also told other Republic customers that it was suing Republic in connection with the relabeled display boxes.

FN6. Republic states that Eby-Brown and

> Clark were longtime participants in its incentive programs. *Id.* ¶ 34.

Furthermore, Republic claims that Jay Martin, North Atlantic's chief operating officer, told representatives of five nationwide tobacco-product distributors (who were also Republic's customers) that Republic's programs were illegal. This statement allegedly occurred at a meeting in Chicago in late July 1998. Republic asserts that Martin also told the representatives that North Atlantic had initiated litigation against Republic, but Martin failed to tell them that Republic had first filed the instant case. Less than two months after the meeting, Garber Brothers, Inc., one of the distributors represented at the meeting, discontinued its participation in Republic's incentive programs and told Republic it anticipated no future purchases of Republic's JOB brand cigarette papers. *Id.* ¶¶ 37-40.

***3** Republic also alleges that, in mid-August 1998, North Atlantic sent a letter (the "August letter") to its customers, many of whom are also Republic customers. The August letter states that North Atlantic filed a lawsuit against Republic in Kentucky, and describes North Atlantic's allegations in that suit.[FN7] The allegations address, among other things, Republic's incentive programs and use of the display boxes. *Id.*, Ex. G. Republic asserts that the August letter falsely suggests that Republic will be unable to honor its obligations under its incentive programs, and that customers who received the letter are now concerned about the status of Republic's incentive programs.*Id.* ¶¶ 41-43.

> FN7. Republic notes that the August letter failed to mention the instant action. *Id.* ¶ 44.

Republic contends that North Atlantic's alleged misstatements have caused Republic to lose sales and have discouraged Republic's customers from participating in its incentive programs. *Id.* ¶ 46.

Pricing Practices

Republic also alleges that North Atlantic has engaged in anticompetitive pricing practices. The amended complaint states that "North Atlantic has leveraged ZIG-ZAG's market power to increase prices much faster than the rate of inflation."*Id.* ¶ 51.Republic claims that North Atlantic "prices products of like grade and quality differently" and that it uses this differential pricing to reinforce its market share. *Id.* ¶ 52.Republic also asserts that North Atlantic uses "leveraging tactics," such as making promotions of one product available only to customers who agree to purchase other products, to add new distributors and retailers. *Id* . ¶ 54-55.

The Pending Actions

On June 30, 1998, Republic filed a four-count complaint in the instant case against NATC and NAOC. After NATC and NAOC moved to dismiss several counts of the complaint, we gave Republic leave to amend. Republic filed an amended complaint on September 16, 1998, which added National as a defendant.

On July 15, 1998, NAOC and National filed an action against Republic and its affiliated companies in the United States District Court for the Western District of Kentucky (the "Kentucky action"), primarily alleging antitrust violations. The two pending actions have some overlapping facts; thus, all matters relating to discovery in both cases are being heard in this court.[FN8]

> FN8. In a minute order dated September 2, 1998, we denied defendants' motion to transfer or stay these proceedings.

In the instant case, Republic seeks declaratory relief regarding patent noninfringement (Count I) and trademark noninfringement (Count II). It also seeks declaratory relief that its incentive programs do not violate federal antitrust laws (Count III). Republic alleges a variety of other claims against defendants, including tortious interference with customer relationships (Count IV); false advertising in violation of the Lanham Act (Count V); violation of the Uniform Deceptive Trade Practices Act (Count VI); violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (Count VII); defamation (Count VIII); unfair competition (Count IX); and unlawful monopolization and attempted monopolization in violation of the Sherman Act (Count X). North Atlantic moves to dismiss Counts I, IV, V, VII, VIII, IX, and X for failure to state a claim upon which relief can be granted.

***4** Furthermore, North Atlantic has asserted a

counterclaim in this case, which Republic moves to "strike." Republic's motion is more appropriately characterized as a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted, and we treat it accordingly.

DISCUSSION

A. Defendants' Motion to Dismiss

The purpose of a 12(b)(6) motion to dismiss is to test the sufficiency of the complaint, not to resolve the case on the merits. 5A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1356, at 294 (2d ed.1990). When evaluating such a motion, the court must accept as true all factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *Jang v. A.M. Miller & Assocs.*, 122 F.3d 480, 483 (7th Cir.1997); *Travel All Over the World, Inc. v. Kingdom of Saudi Arabia*, 73 F.3d 1423, 1429 (7th Cir.1996). Dismissal is appropriate only if " 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." ' *Ledford v. Sullivan*, 105 F.3d 354, 356 (7th Cir.1997) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)); *Jones v. General Elec. Co.*, 87 F.3d 209, 211 (7th Cir.), *cert. denied*,117 S.Ct. 510 (1996).

The Seventh Circuit has held that, under the liberal system of notice pleading envisioned by Federal Rule of Civil Procedure 8,

complaints need not contain elaborate factual recitations. They are supposed to be succinct.... Any need to plead facts that, if true, establish each element of a "cause of action" was abolished by the Rules of Civil Procedure in 1938, which to signify the radical change from code pleading also replaced "cause of action" with "claim for relief." One pleads a "claim for relief" by briefly describing the events. At this stage the plaintiff receives the benefit of imagination, so long as the hypotheses are consistent with the complaint.

Sanjuan v. American Bd. of Psychiatry & Neurology, Inc., 40 F.3d 247, 251 (7th Cir.1994) (citations omitted), *cert. denied*,516 U.S. 1159 (1996).

Count I-Declaratory Relief Regarding Patent Infringement

In Count I of its amended complaint, Republic seeks declaratory relief pursuant to 28 U.S.C. § 2201(a)-specifically, a declaration that North Atlantic holds no valid patent in the cigarette paper display boxes, that Republic has not infringed any valid patent in them, and that the display boxes may be used by Republic and its customers "for whatever lawful purpose they desire."Amended Complaint at 16.

North Atlantic argues that it does not claim that it has a patent for the display boxes and that we should dismiss this count because it presents no "actual controversy" as required by 28 U.S.C. § 2201 to award relief.[FN9] North Atlantic submits the affidavit of Jeffrey S. Hay, Executive Vice President and General Counsel of NATC and NAOC. Defendants' Memorandum in Support of Motion to Dismiss Counts I, IV, V, VII, VIII, IX and X of the Amended Complaint ("Defendants' Memorandum"), Ex. A ("Hay Affidavit"). Hay states that "on June 3, 1998, I specifically informed Seth I. Gold, Republic's Executive Vice President and in-house counsel, that North Atlantic did not claim any patent rights in the [display boxes] and that North Atlantic patent rights were not at issue in the dispute between North Atlantic and Republic."Hay Affidavit, ¶ 4.

> FN9. Thus, North Atlantic's motion to dismiss Count I is not a Rule 12(b)(6) motion for failure to state a claim; rather, it is a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction. When considering a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction, a district court accepts as true all well-pled factual allegations and draws reasonable inferences from the allegations in favor of the plaintiff. *Capitol Leasing Co. v. FDIC*, 999 F.2d 188, 191 (7th Cir.1993). The court may also look beyond the allegations of the complaint and consider affidavits and other documentary evidence to determine whether subject matter jurisdiction exists. *Id.*

***5** The Declaratory Judgment Act, 28 U.S.C. § 2201, allows federal courts to render declaratory judgments only when an "actual controversy" exists.*Crown Drug Co. v. Revlon, Inc.*, 703 F.2d 240, 243 (7th

Cir.1983).“[T]he question ... is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.”*Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941).“ ‘The defendant must have engaged in conduct giving rise to a reasonable apprehension on plaintiff's part that it will face ... suit or the threat of one if it commences or continues the activity in question.” ’ *Trippe Mfg. Co. v. American Power Conversion Corp.*, 46 F.3d 624, 627 (7th Cir.1995) (quoting *International Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210 (7th Cir.1980)). “The focus of the inquiry must rest on the defendant's statements and conduct ....” *Id.*Because the crucial date for determining whether a federal court has jurisdiction is the date the complaint was filed, *see Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734 n. 2 (Fed.Cir.1988), we must confine our analysis to factual developments occurring before the June 30, 1998 filing of the complaint.

Republic argues that North Atlantic's statements to Republic's customers regarding its patent rights, coupled with its direct threats of filing suit against Republic for violating unspecified laws, gave Republic a “reasonable apprehension” at the time of filing this suit “that North Atlantic would continue to harass its customers and threaten litigation without seeking judicial resolution of the parties' dispute.”Plaintiff Republic Tobacco, L.P.'s Response Brief in Opposition to Defendants' Motion to Dismiss Counts I, IV, V, VII, IX and X of the Amended Complaint (“Response”) at 9-10.[FN10]Perhaps this is true, but the key question is whether Republic had a reasonable apprehension of *litigation* itself-more specifically, litigation regarding a patent claim made by North Atlantic.

> FN10. Apparently, Republic inadvertently omitted “Count VIII” from the title of its Response.

We consider relevant the fact that Hay, North Atlantic's general counsel, told Gold, Republic's in-house counsel, that there were no patent rights at issue regarding the display boxes. Hay states that he specifically told Gold so on June 3, 1998.[FN11]These circumstances strongly suggest that Republic did not have a reasonable apprehension that it would face a patent infringement suit with respect to the display boxes.

> FN11. The statements would therefore negate any impression to the contrary created by the Czerewko letter, which was sent in late January 1998. Thus, we need not consider whether Czerewko even had the authority to make charges of patent infringement.

More importantly, there is no evidence that North Atlantic holds a patent for the display boxes. And no justiciable case or controversy exists where there is no issued patent for the court to declare “invalid” or “not infringed”:

[D]efendant argues that ... nowhere in the patent laws is a cause of action created for the alleged infringement of an invention that has never been patented. Accordingly, since defendant could not sue under the patent laws for damages for infringement of a nonexistent patent, plaintiff may not use the declaratory judgment device to accomplish the same result. This court must agree with this contention.

***6** *Pittway Corp. v. BRK Shareholders' Comm.*, 444 F.Supp. 1210, 1214 (N.D.Ill.), *aff'd*,588 F.2d 835 (7th Cir.1978) (citation omitted); *see also GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 482 (Fed.Cir.1996) (“We ... hold that a threat is not sufficient to create a case or controversy unless it is made with respect to a patent that has issued before a complaint is filed .”). Accordingly, Count I is dismissed.

Count IV-Tortious Interference with Customer Relationships

In Count IV of its amended complaint, Republic alleges that defendants tortiously interfered with its customer relationships. Republic claims that North Atlantic wrongfully induced Republic's customers to end or diminish certain business relationships with Republic, leading to lost sales. This tort generally is recognized in Illinois as “tortious interference with prospective economic advantage.”*See, e.g., Dowd & Dowd, Ltd. v. Gleason*, 693 N.E.2d 358 (Ill.1998).

To state a claim for tortious interference with prospective economic advantage, a plaintiff must allege four elements: 1) a reasonable expectation of a valid business relationship or economic advantage; (2) the defendant's knowledge of the expectancy; (3) purposeful interference by the defendant that defeats the expectancy; and (4) damages to the plaintiff resulting from the interference. *See* *Douglas Theater Corp. v. Chicago Title & Trust Co.*, 641 N.E.2d 584, 590 (Ill.App.Ct.1994).

North Atlantic argues that Republic fails to allege the requisite interference because the interference must induce a breach or termination of the business relationship or expectancy. North Atlantic contends that Republic has not alleged that any of Republic's customers stopped doing business with Republic altogether; rather, Republic has only alleged that certain customers stopped participating in its incentive programs and that one customer told Republic it did not anticipate further purchases of a certain brand of Republic cigarette papers.

North Atlantic cites several Illinois cases that purportedly support its strict view that Republic must allege that a customer ceased doing business with it altogether. However, those cases merely stand for the proposition that "the interference complained of must induce or cause a breach or termination of the relationship or expectancy."*Heying v. Simonaitis*, 466 N.E.2d 1137, 1141 (Ill.App.Ct.1984). Nowhere do the Illinois cases say that the interference complained of must cause a complete termination of the entire business relationship between plaintiff and a third party. The cases refer, significantly, to a relationship *or* expectancy.

Even if the Illinois cases did require a complete termination of a business relationship, Republic's amended complaint would still pass muster under the liberal standards of federal notice pleading. While a plaintiff in state court might be required to allege all facts necessary to recover under his chosen legal theory, that is not the case in federal court. *See* *Albiero v. City of Kankakee*, 122 F.3d 417 (7th Cir.1997). In the federal notice pleading system, a claim should not be dismissed so long as it is possible to hypothesize facts, consistent with the complaint, that would make out a claim for relief. Not only is it possible, but it is easy for the court to hypothesize that one or more of Republic's customers terminated its relationship with Republic as a result of the alleged actions of North Atlantic. Accordingly, defendants' motion to dismiss is denied as to Count IV.

Count V-Lanham Act

***7** In Count V of its amended complaint, Republic alleges that North Atlantic made false statements to Republic's customers regarding Republic's incentive programs and use of the display boxes, and thereby violated § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

The Lanham Act provides a cause of action for false description or presentation, known as a "false advertising" claim. Section 43(a) of the Lanham Act provides in relevant part:

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any ... false or misleading description of fact, or false or misleading representation of fact, which-

...

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). A statement constitutes "commercial advertising or promotion" when it is "(1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendants' goods or services; and (4) disseminated sufficiently to the relevant purchasing public."*See* *Liberty Tel. Co. v. Burke*, No. 96 C 50381, 1997 WL 177140, at *5 (N.D.Ill. Mar. 31, 1997) (citing *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1384 (5th Cir.1996)).

The only factor at issue here is whether North Atlantic's statements were disseminated sufficiently to the relevant purchasing public. North Atlantic contends that all the alleged statements were not

made to the purchasing public, but rather to "middlemen" in the distribution chain. Reply at 6. North Atlantic also contends that "an isolated letter or other communication is not 'advertising' or 'promotion' under the Lanham Act."Defendants' Memorandum at 5. North Atlantic relies primarily on *American Needle & Novelty, Inc. v. Drew Pearson Marketing, Inc.*, 820 F.Supp. 1072 (N.D.Ill.1993), where the court held that a single letter, privately addressed to a non-consuming licensor of sports-logo head wear, did not constitute commercial advertising or promotion.*Id.* at 1078.But *American Needle* also recognized that "[t]he level of circulation required to constitute advertising and promotion will undeniably vary from industry to industry and from case to case."*Id.* The resolution of the issue depends on how an industry advertises or promotes its goods or services, and in some cases, "where the potential purchasers in the market are relatively limited in number, a single promotional presentation may be enough to trigger the protections of section 1125(a)."*Liberty Tel.*, 1997 WL 177140, at *5. Thus, whether North Atlantic's statements constituted advertising or promotion depends on how Republic and North Atlantic's industry advertises or promotes RYO cigarette papers and on the size of their relevant purchasing public.

***8** North Atlantic's arguments are unpersuasive. First, Republic does not base its Lanham Act claim on a single, privately addressed letter, as was the case in *American Needle.*Rather, Republic claims that North Atlantic made false and misleading statements on several different occasions. Moreover, North Atlantic conveniently glosses over the word "relevant" in the term "relevant purchasing public." The Lanham Act does not require allegedly false statements to reach the ultimate consumer before they are actionable. *See American Needle*, 820 F.Supp. at 1077;*Health Care Compare Corp. v. United Payors & United Providers, Inc.*, No. 96 C 2518, 1998 WL 122900, at *4 (N.D.Ill. Mar. 13, 1998) ("We think it is enough if the false advertising is directed to an identifiable group that the advertiser seeks to persuade for the purpose of enhancing its competitive position, directly or indirectly, with the consuming public."). We can infer from the amended complaint that the promotion and marketing of RYO cigarette papers is directed at distributors, wholesalers, and retailers. Amended Complaint, ¶¶ 5-6. Therefore, those "middlemen" are the relevant purchasing public for Lanham Act purposes. Furthermore, Republic alleges that North Atlantic's statements were made to a substantial number of the middlemen. *Id.* ¶ 72.These allegations sufficiently state a claim under § 43(a) of the Lanham Act.

North Atlantic also argues, to no avail, that the statements it allegedly made do not fall within the category of speech governed by § 43(a) of the Lanham Act because they "do not address Republic's goods or services."Defendants' Memorandum at 6. The plain language of § 43(a) provides a remedy for misrepresentations relating to "goods, services, *or commercial activities.* " 15 U.S.C. § 1125(a)(1)(B) (emphasis added).[FN12] North Atlantic's alleged misrepresentations relate to Republic's incentive programs and use of the display boxes, which constitute "commercial activities." North Atlantic's motion to dismiss is denied as to Count V.

> FN12. The Trademark Law Revision Act of 1988, amending and expanding § 43(a) of the Lanham Act, added the "commercial activities" language.

Count VII-Illinois Consumer Fraud and Deceptive Business Practices Act

In Count VII of its amended complaint, Republic alleges that defendants' false and misleading statements to Republic's customers about Republic's trade programs and refurbished display boxes constituted unfair and deceptive business practices in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (the "Consumer Fraud Act"), 815 Ill. Comp. Stat. Ann. § 505/2. North Atlantic argues that, for a dispute between two businesses to fall within the protections of the act, the alleged conduct must implicate consumer protection concerns. Defendants' Memorandum at 8. North Atlantic asserts that Republic fails to state a claim under the Consumer Fraud Act by failing to allege this consumer nexus.

The Consumer Fraud Act provides in relevant part:

Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression, or omission of any material fact, with intent that others rely upon the

concealment, suppression or omission of such material fact ... are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

***9** 815 Ill. Comp. Stat. Ann. 505/2.

Claims under the Consumer Fraud Act must meet the consumer nexus test by alleging that the complained-of conduct "involves trade practices directed to the market generally or otherwise implicates consumer protection concerns."*Athey Prods. Corp. v. Harris Bank Roselle*, 89 F.3d 430, 436-37 (7th Cir.1996); *see also Brody v. Finch Univ. of Health Sciences/The Chicago Med. Sch.*, 698 N.E.2d 257, 269 (Ill.App.Ct.1998); *Lake County Grading Co. v. Advance Mechanical Contractors, Inc.*, 654 N.E.2d 1109, 1115-16 (Ill.App.Ct.1995).

Republic argues that the amended complaint alleges that North Atlantic's misrepresentations were directed to the market generally-the "relevant consuming public" of Republic's products, distributors and retailers. Response at 16. We are unpersuaded. Alleged statements to distributors and retailers do not constitute the required connection to consumers. Republic also argues that "North Atlantic's false statements also implicate consumer protection concerns by wrongfully diverting sales from Republic, thereby affecting the supply of Republic's products available for purchase by consumers."*Id.* at 17. This claimed consumer connection is far too indirect to satisfy the consumer nexus requirements. Because the amended complaint fails to identify any misrepresentation by defendants which affected a consumer or implicated consumer protection concerns, it does not state a claim under the Consumer Fraud Act. It may be, however, that Republic could supply these missing allegations in an amended Count VII. Therefore, North Atlantic's motion to dismiss Count VII is granted, with leave to amend granted to Republic to allege facts showing a consumer nexus if it can do so.

Count VIII-Defamation

North Atlantic next challenges Count VIII of Republic's amended complaint, which alleges that North Atlantic's false statements to Republic's customers about the display boxes and incentive programs damaged Republic's reputation, sales, and customer relationships.

Under Illinois law, the elements of a claim for defamation are (1) a false statement concerning plaintiff; (2) defendant's unprivileged publication of that statement to a third party; and (3) damage to the plaintiff. See *Krasinski v. United Parcel Service, Inc.*, 530 N.E.2d 468, 471 (Ill.1988).

North Atlantic first argues that the amended complaint does not allege the first element of defamation-that North Atlantic made false statements. North Atlantic contends that the August letter simply states that North Atlantic's "*complaint alleges* " that Republic's activities are illegal, and that this statement is true because "North Atlantic *has* filed a complaint and that complaint *does* allege that Republic's ... practices are unlawful."Defendants' Memorandum at 9.

An examination of the August letter reveals that each sentence that refers to the allegations in the Kentucky action does begin with a phrase similar to "the complaint alleges." But it is plain that North Atlantic was conveying the substance of its allegations to Republic's customers, not the mere fact that the allegations had been made. And it is the substance of those allegations that Republic is claiming to be false. North Atlantic cannot preface defamatory statements with the words "the complaint alleges" and then claim that the statements are literally true. We hold, therefore, that Republic's allegations of falsity in relation to the August letter, in addition to the Czerewko letter and the Martin meeting, are sufficiently pleaded.

***10** North Atlantic also contends that Republic cannot state a claim of defamation based on the August letter, the Czerewko letter, or the Martin meeting statements because each of those communications was absolutely privileged as related to a judicial proceeding. This argument fails. North Atlantic accurately states that, under Illinois law, statements made preliminary to or during a judicial proceeding are absolutely privileged if the statements relate to the proceeding. *See Bushell v. Caterpillar, Inc.*, 683 N.E.2d 1286, 1287-88 (Ill.App.Ct.1997). But North Atlantic fails to recognize that the privilege applies only when the defendant is acting in furtherance of some interest of social importance.[FN13]The privilege does not apply if the

statements are made to parties not involved in the suit or through improper channels. *See* *Thomas v. Petrulis*, 465 N.E.2d 1059, 1064 (Ill.App.Ct.1984). Here, the statements were made to third parties. Moreover, there is some dispute over whether they related to proposed litigation. The court cannot determine on a motion to dismiss whether the alleged statements were pertinent to proposed litigation.

> FN13. And in its Reply, North Atlantic makes a misleading statement in reference to this court's opinion in *Jernryd v. Nilsson*, No. 84 C 7551, 1985 WL 3590, at *17 (N.D.Ill. Nov. 8, 1985). North Atlantic states: "In *Jernryd*, this Court recognized that the judicial privilege protects all statements, regardless of their purpose, if they are relevant to proposed or pending litigation."Reply at 13. But North Atlantic fails to acknowledge our statement just four sentences below: "[I]f the statements are made to parties not involved in the suit or through improper channels, the privilege does not apply."North Atlantic should be more careful in its citation of authority.

Defendants' motion to dismiss is denied as to Count VIII.

Count IX-Unfair Competition

In Count IX of the amended complaint, Republic alleges that defendants' false statements to Republic's customers regarding Republic's refurbished display boxes and trade programs constitute unfair competition and have damaged Republic. North Atlantic argues that this claim fails under Illinois law because "Republic does not allege that North Atlantic engaged in any conduct that would result in confusion as to the source of the parties' goods."Defendants' Memorandum at 11.

A review of Illinois law and reference to other federal courts dealing with this issue reveals that Illinois courts recognize only two types of unfair competition actions: (1) tortious interference with prospective economic advantage; and (2) trademark-type likelihood of confusion claims. *See* *WorldCom, Inc. v. Transcend Allegiance, Inc.*, No. 97 C 6150, 1998 WL 111636, at *2 (N.D.Ill. Mar. 6, 1998) ("Despite more reaching grounds for unfair competition in other jurisdictions, Illinois courts have limited these suits to tortious interference and trademark or trademark-type claims.") (citing *Barry Gilberg, Ltd. v. Craftex Corp.*, 665 F.Supp. 585, 597 (N.D.Ill.1987)).

Republic has stated a tortious interference claim; therefore, its unfair competition claim would have to be premised on likelihood of confusion-that "the adoption and use of a product name by a defendant is likely to cause confusion in the trade as to the source of the products or is likely to lead the public to believe that defendant is in some way connected with the plaintiff."*Barry Gilberg,* 665 F.Supp. at 597 (citing *Lady Esther v. Lady Esther Corset Shoppe*, 46 N.E.2d 165 (Ill.App.Ct.1943)).[FN14] Republic alleges nowhere that North Atlantic engaged in conduct that would result in confusion as to the source of the parties' goods. Consequently, we grant defendants' motion to dismiss Count IX.

> FN14. The cases cited by Republic are inapposite because they did not address Illinois unfair competition law. *Wilson v. Electro Marine Systems, Inc.*, 915 F.2d 1110 (7th Cir.1990), discusses New York law; *Stephen & Hayes Construction Co. v. Meadowbrook Homes, Inc.*, 988 F.Supp. 1194 (N.D.Ill.1998), relies on *Wilson* without analyzing Illinois law.

Count X-Sherman Act

***11** In Count X of its amended complaint, Republic alleges that North Atlantic violated § 2 of the Sherman Act, 15 U.S.C. § 2. Section 2 allows plaintiffs to proceed under two separate theories of recovery-monopolization and attempted monopolization.[FN15]

> FN15.Section 2 of the Sherman Act makes it an offense for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States."15 U.S.C. § 2.

To state a claim for monopolization under § 2, Republic must allege that (1) North Atlantic possesses monopoly power in a defined, relevant

market; and (2) North Atlantic willfully acquired or maintained that power, as distinguished from growth or development due to a superior product, business acumen, or historic accident. *See* United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966). To state a claim for attempted monopolization under § 2, Republic must allege that (1) North Atlantic had the specific intent to acquire monopoly power; (2) North Atlantic engaged in anticompetitive or predatory conduct to further its goal of monopolization; and (3) there is a dangerous probability of North Atlantic's success in acquiring monopoly power. *See* Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993). Monopoly power is the power to control prices or exclude competition. *See* Grinnell, 384 U.S. at 571.

Thus, a § 2 claim under either theory requires Republic to allege that North Atlantic holds, or that there is a dangerous probability of North Atlantic gaining, monopoly power. Republic defines the relevant market as "the nationwide market for distribution of RYO cigarette papers," and then alleges that North Atlantic maintains a market share of approximately 50% in that market. Amended Complaint, ¶ 90. We cannot infer monopoly power simply on the basis of this market share because 50% does not constitute predominance. *See* Grinnell, 384 U.S. at 571.

That does not end the inquiry, for the existence of monopoly power depends upon a variety of market characteristics in addition to market share, such as "the strength of the competition, the probable development of the industry, the barriers to entry, the nature of the anticompetitive conduct and the elasticity of consumer demand."*International Distrib. Ctrs., Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 792 (2d Cir.1987). Republic alleges that North Atlantic itself has stated that the RYO cigarette paper market has "significant barriers to entry," and that North Atlantic's ZIG-ZAG brand papers are the number-one seller in the United States. Amended Complaint, ¶¶ 7, 8. These allegations alone do not allow us reasonably to infer that North Atlantic has, or that there is a dangerous probability of its acquiring, the power to control prices or to exclude competition.[FN16]Accordingly, Republic fails to state a § 2 claim for monopolization or attempted monopolization. Defendants' motion to dismiss Count X of the amended complaint is granted.

FN16. We therefore need not address the other elements of § 2 claims.

B. Plaintiff's Motion to Strike the Counterclaim

Republic moves to "strike" North Atlantic's counterclaim. Rule 12(f) of the Federal Rules of Civil Procedure governs motions to strike and provides that "the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter."However, Republic does not assert that the counterclaim contains any redundant, immaterial, impertinent, or scandalous matter. Rather, it contends that the counterclaim fails to state a claim upon which relief may be granted. Therefore, we treat the motion as a Rule 12(b)(6) motion to dismiss.

***12** North Atlantic's counterclaim states in its entirety:

Defendants have valid claims against plaintiff and other entities that are currently pending in the United States District Court for the Western District of Kentucky in the case captioned *North Atlantic Trading Company, Inc., et al. v. Republic Tobacco, Inc., et al.*, No. 3:98CV-462H ("Kentucky Action"). Those claims are hereby alleged in this action to the extent that they are compulsory counterclaims, and the allegations supporting such compulsory counterclaims that are stated in the Amended Complaint filed in the Kentucky Action are expressly incorporated herein.

Answer and Affirmative Defenses to Amended Complaint, Counterclaims and Third-Party Claims, at 14. Republic argues that this statement is "too vague, too ambiguous, and too contingent to constitute a 'short and plain statement of the claim"' as required by Federal Rule of Civil Procedure 8(a). Plaintiff Republic Tobacco, L.P.'s Memorandum in Support of Its Motion to Strike Counterclaim at 4. Republic also asserts that "[r]ather than putting Republic on notice, the counterclaim seeks to place the burden on Republic to guess which of North Atlantic's claims are compulsory under Rule 13(a)."*Id.*[FN17]

FN17.Rule 13(a) of the Federal Rules of Civil Procedure deals with compulsory counterclaims and provides in relevant part:

> A pleading shall state as a counterclaim any claim which at the time of serving the pleading the pleader has against any opposing party, if it arises out of the transaction or occurrence that is the subject matter of the opposing party's claim ....

North Atlantic responds that Republic's argument is "spurious" because Republic answered the amended complaint in the Kentucky action and is therefore on notice of all of defendants' claims that are compulsory counterclaims in this action. Defendants' Opposition to Plaintiff's Motion to Strike Counterclaims at 1-2. North Atlantic adds that "[t]here is no need at this time to address which, if any, of NAOC's and National's claims are compulsory counterclaims in the present action."*Id.* at 2.

We disagree. Federal Rule of Civil Procedure 8(a) requires only a "short and plain statement of the claim," but it is axiomatic that such a statement must give the opposing party fair notice of what the claim is and the grounds upon which it rests. *See* *Conley v. Gibson*, 355 U.S. 41, 47 (1957). North Atlantic's counterclaim is not sufficiently specific to put Republic on notice of the claims against it. And while North Atlantic may believe that it is not necessary to determine at this point which of its Kentucky claims are compulsory counterclaims, Rule 13 requires North Atlantic to identify its compulsory counterclaims, if any, in its answer. *See also* *Harbor Ins. Co. v. Continental Bank Corp.*, 922 F.2d 357, 360 (7th Cir.1990) ("A compulsory counterclaim is compulsory; unless set forth in the answer to the complaint it is waived."). The existence of the Kentucky proceeding does not relieve North Atlantic of this obligation. Therefore, defendants' counterclaim is dismissed with leave to amend.

CONCLUSION

For the foregoing reasons, we grant defendants' motion to dismiss Counts I, VII, IX, and X of the amended complaint, and we deny defendants' motion to dismiss Counts IV, V, and VIII. Plaintiff may have until April 30, 1999 should it wish to replead Count VII to allege facts indicating a consumer nexus.

***13** We grant plaintiff's motion to dismiss defendants' counterclaim for failure to state a claim. Defendants may have until April 30, 1999 to file an amended counterclaim in compliance with this opinion.

N.D.Ill.,1999.
Republic Tobacco, L.P. v. North Atlantic Trading Co.
Not Reported in F.Supp.2d, 1999 WL 261712 (N.D.Ill.), 1999-1 Trade Cases P 72,554

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APPENDIX 2

Westlaw.
Not Reported in F.Supp. Page 1
Not Reported in F.Supp., 1998 WL 122900 (N.D.Ill.), 1998-1 Trade Cases P 72,181
1998 WL 122900 (N.D.Ill.)

Health Care Compare Corp. v. United Payor & United Providers, Inc.
N.D.Ill.,1998.

United States District Court, N.D. Illinois.
HEALTH CARE COMPARE CORP. d/b/a the Affordable Medical Networks Plaintiff,
v.
UNITED PAYORS & UNITED PROVIDERS, INC., a Delaware corporation, d/b/a/ UP & UP, corporately and as successor-in-interest to PB Newco, Inc.., an Iowa corporation and United Payors & United Providers, Inc., a Maryland corporation, d/b/a/ UP & UP; One or More John or Jane Does; and One or More Coe Entities, Defendants.
No. 96 C 2518.

March 13, 1998.

MEMORANDUM AND ORDER

MORAN, Senior J.
***1** Plaintiff HealthCare Compare Corp. (HealthCare) has brought a six-count complaint against defendant United Payors & United Providers, Inc. (United Payors), in which it alleges that United Payors is liable for (1) false designation of origin under the Lanham Act, 15 U.S.C. 1125(a)(1)(A) (Count I); (2) false advertising under the Lanham Act, 15 U.S.C. 1125(a)(1)(B) (Count II); (3) fraud and deceptive trade practices under the Illinois Deceptive Trade Practices Act, 815 ILCS 510/1*et seq.*, including § 510/2(2), (3), (5) and (12), incorporating by reference the Lanham Act claims (Count III); (4) fraud and deceptive business practices under the Illinois Consumer Fraud Act, 815 ILCS 505/1*et seq*, incorporating by reference the Lanham Act claims (Count IV); (5) intentional interference with contracts under state law, incorporating by reference the Lanham Act claims (Count V); and (6) unfair competition under state law, incorporating by reference the Lanham Act claims (Count VI).

Defendant United Payors has moved for summary judgment on Count II and all related state law claims. For the reasons stated below we deny this motion in its entirety.

BACKGROUND

HealthCare and United Payors are two companies that operate health care networks. HealthCare operates a preferred provider organization (PPO) under the name, "The *AFFORDABLE* Medical Network." The network forms contracts with two distinct types of entities, "payors" and "providers." "Payors" is the term used to describe insurance companies, self-insured employers, employee groups, and any other entity seeking to purchase access to health services providers on behalf of their constituent members (*ie.*, the insureds and the employees). "Providers" are the doctors and hospitals who provide the desired health care services. HealthCare acts as an intermediary between these two groups. On one hand, HealthCare enters into agreements with the payors wherein the payors agree to pay a fee to HealthCare and in exchange are given access to discounted medical services that HealthCare contracts to receive from the providers. On the other side, HealthCare forms contracts with the providers wherein the providers agree to provide medical services at a discounted rate in exchange for access to the needs of the payors in HealthCare's network. HeathCare's PPO is considered a "directed" network because its agreements with payors require the payors to create financial and other incentives to encourage their members to use the medical providers in the PPO.

United Payors is also a health care network company with a structure and function similar to HeathCare's. United Payors enters into agreements with both providers and payors. Instead of being a "directed" network, however, United Payors operates under "quick pay" procedures and does not require its payor-clients to create financial incentives and other devices to channel their members to the plan providers.

***2** In the course of soliciting business from providers, United Payors informs the providers of the number of"covered lives" that participate in its payor clients' plans and sends copies of a "Payor Directory" to the providers. These directories list the participating payors, but do not state whether the payors have an

obligation to create incentives for their members to use the participating providers. Additionally, United Payors has contacted several of the providers with which HealthCare has provider agreements, distributed the directories to those providers and made statements indicating HealthCare and United Payors are somehow related, as well as other false and misleading representations.[FN1]

> FN1. For purposes of the motion for summary judgment presently before the court, United Payors has agreed to accept the facts in HealthCare's complaint as true (insofar as they are relevant to the instant motion).

HealthCare subsequently brought this action against United Payors alleging, among other things, that the statements United Payors made to the providers constitute "false advertisement" under the Lanham Act.

ANALYSIS

A. Standard of Review

A motion for summary judgment may be granted where the pleadings and evidence present no genuine issues of fact and the movant is consequently entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Renovitch v. Kaufman*, 905 F.2d 1040, 1044 (7th Cir.1990). The movant must point to those portions of the record which demonstrate the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Summary judgment should be entered against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Id.* at 322. The reviewing court shall draw all reasonable inferences in favor of the non-movant. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970); *Bank Leumi Le-Israel, B.M. v. Lee*, 928 F.2d 232, 236 (7th Cir.1991). When it is clear that the plaintiff cannot carry her burden of persuasion at trial on one or more elements, summary judgment is appropriate for the defendant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

B. The Lanham Act

The Lanham Act provides two distinct causes of action to prevent consumer confusion regarding product's source: false designation of origin or source, known as "product infringement" claims, and false description or presentation known as "false advertising" claims. *Agee v. Paramount Communications Inc.*, 853 F.Supp. 778 (S.D.N.Y.1994)*aff'd in part, rev'd in part*59 F.3d 317 (1995). Plaintiffs second amended complaint alleges violations of both sections, but defendant has moved for summary judgment only with respect to Count II, which involves the latter type of claim and is governed by 15 U.S.C. § 1125(a)(1)(B). That section provides:

(a)(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any ... false or misleading description of fact, or false or misleading representation of fact, which-

***3** (A) * * *

(B) *in commercial advertising or promotion,* misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a) (emphasis added). United Payors contends that it is entitled to summary judgment on Count II on the grounds that the statements United Payor allegedly made to its providers do not constitute commercial "advertising" for the purposes of the Lanham Act and, consequently, are not actionable under the above section.

In order for a statement to amount to "commercial advertising or promotion," the statements must be "(1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendants' goods or services; and (4) disseminated sufficiently to the relevant purchasing public." *Liberty Telephone Co., Inc. v. Burke*, 1997 WL 177140

(N.D.Ill.1997)*citing* Seven-Up Co. V. Coca-Cola Co., 86 F.3d 1379, 1384 (5th Cir.1996) (other supporting citations omitted).

United Payors argues that the relationship between itself and its providers could not have involved "advertising" because any statements made in an effort to form the resulting contracts were not made for the "purpose of influencing *consumers to buy* [its] goods or services" and were not disseminated to the "*relevant purchasing public* " (elements 3 and 4 above). United Payors contends that the true "consumers" of its services are the payor entities (the employers and health insurance companies who buy the discounted services), not the providers (the doctors and hospitals who agree to provide health-related services at a discount). Consequently, United Payors argues that it is the payors who constitute the "relevant purchasing public" for purposes of the Lanham Act.

This argument, however, fails to recognize the economic realities present here. United Payors engages itself in two primary types of activities. On the one hand, it forms contracts with payor entities wherein it agrees to provide access to discounted medical services in exchange for the entities' agreement to pay for those services and make them available to the payor's members. On the other hand, United Payors forms contracts with provider entities wherein the provider agrees to sell medical services at below its usual rate in exchange for United Payors' promise to direct its payor clients to use the services of those particular individuals or companies. United Payors cannot succeed unless it persuades both payors and providers to use its services. United Payors "advertising" must be directed to both groups if it is to remain competitive. Both are consumers of United Payors' services, with United Payors providing each with access to the other.

***4** United Payors argues that the providers cannot be considered a "consumer" of United Payors' services on the grounds that they do not pay any sort of fee to United Payors. We do not agree that to be considered a "consumer" for Lanham Act purposes one must pay money for the product or service that is the subject of the alleged false advertising. The statute imposes no such requirement, and neither do the cases. For example, in *Mylan Laboratories, Inc. v. Pharmaceutical Basics, In* ., 808 F.Supp. 446 (D.Md.1992), *rev'd on other grounds*,7 F.3d 1130 (4th Cir.1993), the "advertising" was directed to health care providers by inserts in free samples. Patients were the ultimate purchasing public, but the determining influence upon their purchasing decisions were the recommendations of health care providers. In *American Needle & Novelty, Inc. v. Drew Pearson Marketing, Inc.*, 820 F.Supp. 1072 (N.D.Ill.1993), the alleged false advertising was directed to a licensor that controlled the right to use sports logos, not the retailers selling products bearing sports logos. In *Liberty Telephone v. Burke*, 1997 WL 177140, *1 (N.D.Ill.1997), the parties competed in the placement and servicing of pay telephones in business premises. They received revenue from those using the telephones and, in turn, paid the owner of the business premises a commission. The alleged false advertising was directed to the owners. In all three cases the allegedly false advertising was held to be within the ambit of the statute. We think it is enough if the false advertising is directed to an identifiable group that the advertiser seeks to persuade for the purpose of enhancing its competitive position, directly or indirectly, with the consuming public.

Further, the providers have, in a sense, "paid" United Payors. The payors may pay the cash fee, but that payment is from the margin created by the providers' discount and, indeed, is related to the size of that discount.

Defendant contends that the relationship between providers to United Payors is similar to the relationship between subcontractors and a general contractor and that extending the reach of a false advertising claim to that relationship would extend it, as well, to an ordinary vendor contract in which a seller provides goods or services to a purchaser. We disagree.

It is unclear why such labeling would make a difference in this case. We are interested not in how United Payors labels its relationships with its providers, but in the substance of that relationship. The relevant inquiry is whether the providers can be characterized as "consumers" of United Payors' services for advertising purposes. As discussed earlier, the facts presently known indicate that the providers compose a definite market for United Payors' networking services, that they purchase entry

into the network by discounting their medical services and that their willingness to enter into such contracts could definitely be affected by misstatements about United Payors, HealthCare or any other networking company in that market. We conclude that the providers are in fact members of the "relevant purchasing public" for Lanham Act purposes.

C. The State Law Claims

***5** Defendant United Payors also moves for summary judgment on such of HealthCare's claims that incorporate by reference defendant's Lanham Act claims (Counts III, IV, V and V) These counts are based on Illinois' Deceptive Trade Practices Act, the Consumer Fraud Act, common law intentional interference with contracts and common law unfair competition, respectively. United Payors contends that it is entitled to summary judgment on these claims to the extent that they are based on the allegations used to support Count II, the Lanham Act false advertising claim. Defendant concedes that to the extent the Illinois claims are not based on the false advertising allegations, they are not at issue for purposes of the instant motion.

It is true that claims brought under Illinois' Deceptive Trade Practices Act and Consumer Fraud Act are to be resolved according to principles set forth under the Lanham Act. *Spex, Inc. v. Joy of Spex, Inc.*, 847 F.Supp. 567, 579 (N.D.Ill.1994) However, because we have denied summary judgment on Count II, we obviously cannot grant summary judgment on the state claims solely on the ground that they are co-extensive with Count II. In the absence of any alternative argument in support of defendant's position, we must deny its motion for summary judgment with respect to HealthCare's state law claims.

CONCLUSION

For the reasons stated above, defendant United Payors' motion for summary judgment is denied in its entirety.

N.D.Ill.,1998.
Health Care Compare Corp. v. United Payor & United Providers, Inc.
Not Reported in F.Supp., 1998 WL 122900 (N.D.Ill.), 1998-1 Trade Cases P 72,181

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APPENDIX 3

Healthport Corp. v. Tanita Corp. of America D.Or.,2008.
Only the Westlaw citation is currently available.
United States District Court,D. Oregon.
HEALTHPORT CORPORATION, a Delaware corporation, Plaintiff/Counter-Defendant,
v.
TANITA CORPORATION OF AMERICA, an Illinois corporation, Defendant/Counter-Claimant.
Civil No. 06-419-PK.

May 23, 2008.

David J. Elkanich, Hinshaw & Culbertson, LLP, Portland, OR, Frank Frisenda, Frisenda Quinton & Nicholson, Los Angeles, CA, for Plaintiff/Counter-Defendant.
Evan A. Parke, Joel M. Freed, Kenneth L. Cage, Sudip K. Kundu, McDermott Will & Emery LLP, Michael A. Messina, MC, Washington, DC, J. Christopher Carraway, Todd M. Siegel, Klarquist Sparkman, LLP, Portland, OR, for Defendant/Counter-Claimant.

ORDER

HAGGERTY, Chief Judge.
***1** Magistrate Judge Papak referred to this court a Findings and Recommendation [130] in this matter. The Findings and Recommendation recommends denying plaintiff's motion for summary judgment, granting defendant's motion for summary judgment, and entering judgment and an injunction in this matter. Both parties have filed objections.

When a party objects to any portion of a Findings and Recommendation, the district court must conduct a de novo review. 28 U.S.C. § 636(b)(1)(B); *McDonnell Douglas Corp. v. Commodore Bus. Mach. Inc.*, 656 F.2d 1309, 1313 (9th Cir.1981). Here, the court has performed a de novo review, evaluated the Findings and Recommendation, the objections, and the entire record. Based upon that review, the court agrees with Judge Papak's Findings and Recommendation. [FN1]

The court adopts the Findings and Recommendation [130]. Defendant's Motion for Summary Judgment [99] is GRANTED and plaintiffs Motion for Summary Judgment [100] is DENIED. Healthport Corporation is ORDERED to remove the ELG misrepresentations from its web sites. Healthport Corporation and its officers, directors, agents, employees, and all persons acting in concert with it are PERMANENTLY ENJOINED from publishing or disseminating in any form any advertising or promotional material that contains representations to the effect that the ELG: (1) is the only patented body composition analyzer or metabolic analyzer in the United States or abroad; (2) is patented for unequaled accuracy and validity; (3) is the only body composition analyzer or metabolic analyzer patented for unequaled accuracy and validity; or (4) is unequaled in accuracy and validity as compared to other body composition analyzers. Further, Healthport Corporation and its officers, directors, agents, employees, and all persons acting in concert with it are PERMANENTLY ENJOINED from publishing or disseminating in any form any advertising or promotional material that contains false representations about the credentials of Richard Wooten.

IT IS SO ORDERED.

FINDINGS AND RECOMMENDATION

PAPAK, United States Magistrate Judge.
Healthport Corporation ("Healthport") filed this lawsuit against Tanita Corporation of America ("Tanita") on March 27, 2006, alleging patent infringement related to their competing body composition monitors. On May 26, 2006, Tanita filed two counterclaims alleging Healthport web site advertisements violate the false advertising prong of the Lanham Act and common law unfair competition. (# 11.) Tanita requested money damages along with other forms of relief on its counterclaims.[FN1]

On August 7, 2006, Tanita filed a motion for summary judgment on Healthport's patent infringement claims. (# 18.) The district court adopted this court's Findings and Recommendation (# 61) and granted summary judgment in favor of Tanita and dismissed Healthport's patent claims. (# 70.)

Pending before the court are the parties' cross motions for summary judgment related to Tanita's counterclaims. Tanita seeks summary judgment on its claim for false advertising brought under the Lanham Act.[FN2](# 99.) Healthport Corporation ("Healthport") seeks summary judgment on both of Tanita's counterclaims-false advertising and common law unfair competition. (# 100.) For the reasons set forth below, Tanita's motion for summary judgment should be granted and Healthport's denied.

LEGAL STANDARD

***2** Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law."Fed.R.Civ.P. 56(c). Summary judgment is not proper if material factual issues exist for trial. *See, e.g., Celotex Corp. v. Catrett,* 477 U.S. 318, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *Warren v. City of Carlsbad*, 58 F.3d 439, 441 (9th Cir.1995), *cert. denied*,516 U.S. 1171, 116 S.Ct. 1261, 134 L.Ed.2d 209 (1996). In evaluating a motion for summary judgment, the district courts of the United States must draw all reasonable inferences in favor of the nonmoving party, and may neither make credibility determinations nor perform any weighing of the evidence. *See, e.g., Lytle v. Household Mfg., Inc.*, 494 U.S. 545, 554-55, 110 S.Ct. 1331, 108 L.Ed.2d 504 (1990); *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150, 120 S.Ct. 2097, 147 L.Ed.2d 105(2000).

On cross-motions for summary judgment, the court must consider each motion separately to determine whether either party has met its burden with the facts construed in the light most favorable to the non-moving party. Fed.R.Civ.P. 56; *Fair Housing Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1136 (9th Cir.2001). Summary judgment, of course, may not be granted where the court finds unresolved issues of material fact, even in situations where the cross motions allege that no disputed facts exist. *Id.*

FACTUAL BACKGROUND

A. Healthport Web Sites

Healthport maintains two web sites, which promote or are part of an offering of its web-based services. One web site targets healthcare professionals and offers "an integrated and turnkey Obesity Management & Preventive Medicine System designed to be prescribed by physicians."[FN3](The "CyberCare Plan" web site.) The second web site addresses employers and healthcare benefits providers and offers an online "health risk assessment and individualized 12-week care plan aimed specifically at reducing [an] employee's identified health risk factors."[FN4](The "Health-e-Changes" web site.) Anyone with an Internet connection can access these web sites. The sites do not require a login or password to view them.[FN5]

Tanita's false advertising claim asserts two alleged misrepresentations that appear on the CyberCare Plan and Health-e-Changes web sites. The first describes a Healthport body composition monitor. The other promotes the credentials of Richard Wooten, Healthport's president and chief technology officer.

B. The Body Composition Monitor Advertisement

Both of the Healthport web sites contain descriptions of Healthport's ElectroLipoGraph metabolic analyzer ("ELG"), a body composition monitor. Healthport touts the ELG as "the only metabolic analyzer patented in the United States and abroad for unequaled accuracy and validity in the prediction of human body composition."Healthport goes on to state that the "patented accuracy of the ELG is backed by the largest study on body composition analyzers ever conducted, including more than 750 subjects from a wide demographic population."

***3** To substantiate its claims regarding the ELG, Healthport relies on two studies performed by the University of Southern California. Neither study provides a head-to-head comparison of the ELG with any other body composition monitors. In addition, neither study describes the ELG as having unequaled accuracy. Both studies describe the ELG as an accurate method of measuring body composition. One study adds a note that the ELG is used to measure patients while they are lying down.

Healthport owns two patents related to the ELG.

Healthport relies on these patents to substantiate the claims it makes in the ELG advertisement. However, neither patent suggests that Healthport's ELG has unsurpassed accuracy or validity as compared to other body composition monitors.

C. Richard Wooten Credentials

Richard Wooten serves as Healthport's president and chief technology officer. Both the Healthport web sites offer information about Healthport's management team. That information included statements that Mr. Wooten "received his M.S. degree from Oregon Graduate School of Health Sciences and a B.S. in Biology from Portland State University."Healthport apparently removed Mr. Wooten's credentials from the CyberCare Plan web site in the Summer of 2007, but as of November 2007 the credentials continued to appear on the Health-e-Changes web site. Mr. Wooten admits that he has not earned a college or post graduate degree in any discipline.

ANALYSIS

A. Common Law Unfair Competition

Healthport moves for summary judgment on Tanita's common law unfair competition claim. Healthport asserts that Oregon courts follow federal law when deciding common law unfair competition claims. However, the arguments presented by Healthport address the Oregon Unfair Trade Practices Act, which is not relevant here. Accordingly, Healthport's motion for summary judgment as to the common law unfair competition claim should be denied.

B. False Advertising

Both parties move for summary judgment on Tanita's Lanham Act false advertising claim. Healthport argues that it is entitled to summary judgment because Tanita lacks standing to bring this claim or because Tanita cannot establish causation and injury. Tanita argues that summary judgement in its favor is appropriate because it meets the standing requirements and because the undisputed material facts sufficiently prove its false advertising claim.

1. Lanham Act Standing

The Lanham Act confers standing on "any person who believes that he or she is or is likely to be damaged" by misrepresentations in commercial advertising or promotion. 15 U.S.C. § 1125(a)(1)(B). To establish standing for a false advertising claim brought pursuant to the Lanham Act, a party must allege: "(1) a commercial injury based upon a misrepresentation about a product; and (2) that the injury is 'competitive,' or harmful to the plaintiff's ability to compete with the defendant."*Jack Russell Terrier Network of N. Ca. v. Am. Kennel Club, Inc.*, 407 F.3d 1027, 1037 (9th Cir.2005); *Barrus v. Sylvania*, 55 F.3d 468, 469-70 (9th Cir.1995). Thus, a plaintiff has standing where the alleged misrepresentation could divert business from the plaintiff to the defendant. *See Coastal Abstract Serv. Inc. v. First Am. Ins. Co.*, 173 F.3d 725, 734 (9th Cir.1999) (standing exists where defendant's false statements sought to divert business away from competitor); *Waits v. Frito-Lay, Inc.*, 978 F.2d 1093, 1109 (standing exists for false advertising where misrepresentations about product quality could theoretically draw a consumer away from competitor's product); *see also Barrus*, 55 F.3d at 470 (stating that false advertising discussion in *Waits* is not dicta).

***4** Although Healthport asserts in its motion for summary judgment that no evidence indicates that Tanita and Healthport are competitors, Healthport's own statements suggest otherwise. In its Answer to Tanita's counterclaims, Healthport asserted as its tenth affirmative defense that "Healthport is privileged to lawfully compete with Defendant [Tanita] in market segments."Richard Wooten testified in his deposition that Tanita and Healthport are competitors. Dr. Alfred Libke, Healthport's chairman and CEO, testified that Healthport's ELG competes with Tanita products. Thus, even viewed in the light most favorable to Healthport, ample undisputed evidence demonstrates that Healthport and Tanita are competitors.

Healthport's Motion for Summary Judgment also argues that because it derived no revenue from its web-based CyberCare Plan that Tanita cannot prove it has suffered a competitive injury.[FN6]However, Healthport's arguments miss the mark. Healthport confuses Tanita's allegations as challenging the CyberCare Plan itself, rather than the description of

the ELG and of Mr. Wooten's credentials that are contained within the CyberCare Plan and Health-e-Changes web sites.

The description of Healthport's ELG body composition monitor inherently draws comparisons with competing products, which include Tanita products, and has the potential of diverting business away from Tanita. Both companies offer body composition monitors, and a sale of one of the competing products would result in a denial of a sale for the other. Those facts satisfy the standing requirements for false advertising. Accordingly, this Court rejects Healthport's assertion that Tanita lacks standing for its Lanham Act claim.

2. Lanham Act False Advertising Claim

To prevail on its false advertising claim under the Lanham Act, Tanita must establish that: (1) Healthport made a false statement of fact in a commercial advertisement; (2) the statement deceived or has the tendency to deceive a substantial segment of its audience; (3) the false statement is material in that it is likely to influence the purchasing decision; (4) Healthport caused the false statement to enter interstate commerce; and (5) Tanita has been or is likely to be injured as a result of the false statement. 15 U.S.C. § 1125(a)(1)(b); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir.1997).

a. Element One-Falsity in a Commercial Advertisement

The Lanham Act proscribes misrepresentation in "commercial advertising or promotion." 15 U.S.C. § 1125(a)(1)(B). Representations constitute commercial advertising for Lanham Act purposes if they are 1) commercial speech; 2) by a defendant who is in commercial competition with the plaintiff; 3) for the purpose of influencing consumers to buy the defendant's goods or services and 4) sufficiently disseminated to the relevant purchasing public. *Coastal Abstract Serv.*, 173 F.3d at 735. Commercial speech is "expression related solely to the economic interests of the speaker and its audience."*Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 561, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). A representation is false if a claimant can show that the statement was literally false, false by necessary implication, or literally true but likely to mislead or confuse consumers. *Southland Sod Farms*, 108 F.3d at 1139.

***5** Healthport opposes Tanita's Motion for Summary Judgment on grounds that the statements on the CyberCare plan web site are not commercial advertising or promotion. Neither party disputes that the description of the ELG monitor and of Mr. Wooten's credentials are commercial speech. Healthport is in commercial competition with Tanita. The parties do not dispute that the descriptions appeared on the CyberCare Plan and Health-e-Changes web sites, and that Healthport created those sites to sell health-related services. Finally, the CyberCare Plan and Health-e-Changes sites are accessible to the public. Therefore, the Court finds that the representations constitute commercial advertising for the purposes of the Lanham Act.

The Court further finds that the representations are false. With respect to the statements regarding Mr. Wooten's credentials, the record demonstrates that they are literally false. Healthport has admitted that Mr. Wooten's credentials were manufactured, and Mr. Wooten himself testified that he has not received any college or graduate degrees.

The second statement at issue is Healthport's claim that the ELG is "the only metabolic analyzer patented in the United States and abroad for unequaled accuracy and validity in the prediction of human body composition."Although this statement gives rise to three possible interpretations, the undisputed facts demonstrate that each interpretation is literally false. First, if the statement means the ELG is the only *patented* metabolic analyzer in the United States and abroad, that is a literally false statement. The testimony of both Mr. Wooten and Dr. Lipke revealed that other patented body composition analyzers can perform the same function.

Second, if the statement means the ELG is patented for unequaled accuracy and validity, or that it is the only one patented for those characteristics, that too is literally false. The parties do not dispute that Healthport did not review patents for body composition analyzers when it created the ELG advertisement and thus did not substantiate its assertion. More importantly, ELG's patents do not indicate the patents were awarded for "unequaled

accuracy and validity."

Finally, if the ELG statement means the ELG is unsurpassed in accuracy and validity when compared to other body composition analyzers, Healthport cannot substantiate that claim. Healthport's principals testified they did no comparative or tests to verify their product was "unsurpassed in accuracy and validity." Although Healthport claims to rely on studies to substantiate their claims, those studies simply do not support Healthport's assertions. The studies merely conclude that the ELG is accurate. However, the studies do not suggest the ELG may be more accurate than competing products, nor do the studies compare the ELG with other body composition analyzers. *Southland Sod Farms*, 108 F.3d at 1139 (plaintiff can establish literal falsity if the tests, even if reliable, do not establish the proposition asserted by the defendant).

***6** The statements at issue constitute commercial advertising and are literally false. As a result, Tanita satisfied the first element of its false advertising claim.

b. Elements 2 and 3-Deception and Materiality

Healthport argues that Tanita must prove through the use of consumer surveys or market research that consumers have actually been deceived by the advertisements. Healthport is wrong. Courts may presume consumer deception and reliance if the defendant made an intentionally false statement regarding the defendants' product, even if the statement entailed "little overt reference to plaintiff or plaintiff's product."*Harper House Inc. v. Thomas Nelson, Inc.* ., 889 F.2d 197, 209 (9th Cir.1989) (applying presumption to claim that product cost less than similar products and offered more features); *see also Southland Sod Farms*, 108 F.3d at 1145 ("[T]here need not be a direct comparison to a competitor for a statement to be actionable under the Lanham Act.").

Earlier cases required the expenditure of substantial funds by the defendant before a court would presume consumer deception and reliance. *See Harper House Inc.*, 889 F.2d at 209;*U-Haul Int'l, Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1040-41 (9th Cir.1986). Courts imposed this condition "because the misleading statements may not have reached and deceived a substantial portion of consumers unless the defendant spent enough funds to disseminate the statements widely."*William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 259 n. 2 (9th Cir.1995). In the case of online advertising, however, a defendant need not spend substantial funds to reach a wide audience. *See Allen v. The Ghoulish Gallery*, No. 06-371, 2007 U.S. Dist. LEXIS 86224, 2007 WL 5101179 at*29-30 (S.D.Cal. Nov. 20, 2007). More importantly, courts have found that non-comparative false statements may support a claim for injunctive relief if the claim is material. *See Allen*, 2007 U.S. Dist. LEXIS 86224, 2007 WL 5101179 at*29-30 (S.D.Cal. Nov. 20, 2007) (non-comparative false statement regarding length of time in business was material and sufficient for injunctive relief); *see also Societe Civile Succession Richard Guino v. Beseder Inc.*, No. 03-1310, 2007 U.S. Dist. LEXIS 83782, 2007 WL 3238703, at * 21 (D.Ariz.2007) (non-comparative false statement regarding authenticity of artwork sufficient for injunctive relief). Deception is material if "it is likely to influence the purchasing decision."*Southland Sod Farms*, 108 F.3d at 1139.

Healthport's description of the ELG monitor as "the only metabolic analyzer patented in the United States and abroad for unequaled accuracy and validity in the prediction of human body composition" is a material, false claim regarding its product. Tanita has submitted uncontroverted evidence that the challenged deception is material. Tanita submitted testimony from health professionals who stated that they seek the most accurate equipment for determining body composition and that claims that a metabolic analyzer is the most accurate or the only one patented for accuracy would influence their purchasing decisions. Healthport did not deny these statements. As a result, this statement gives rise to a presumption of consumer deception and reliance. *See Harper House Inc.*, 889 F.2d at 209.

***7** The false statement regarding Mr. Wooten's credentials present a closer issue, as that statement does not directly relate to a Healthport product. However, Dr. Libke, Healthport's co-founder, testified that his advanced medical degree is important to Healthport's customers. Thus, even viewing the evidence in a light most favorable to Healthport, the false statement regarding Mr. Wooten's credentials may deceive consumers and influence consumer decisions on whether to purchase

the ELG body composition monitor. *See*5 McCarthy on Trademarks and Unfair Competition § 27:31 (2008) ("Since § 43(a) was passed to protect consumers as well as competitors, the courts are not and should not be reluctant to allow a commercial plaintiff to obtain an injunction even where the likelihood of provable impact on the plaintiff may be subtle and slight.")

c. Element 4-Interstate Commerce

By posting the Wooten and ELG advertisements on their web sites, Healthport caused the false statements to enter interstate commerce. *See, e.g. U.S. v. Horne*, 474 F.3d 1004, 1006 (7th Cir.2007) (an Internet web site "is an avenue of interstate commerce.")

d. Element 5-Injury

Healthport argues that Tanita's motion for summary judgment should be denied because Tanita has presented no direct evidence of actual injury. However, "because of the possibility that competitor may suffer future injury, as well as the additional rationale underlying section 43(a)-consumer protection-a competitor need not prove injury when suing to enjoin conduct that violates section 43(a)."*Harper House, Inc.*, 889 F.2d at 211. To the extent that Tanita seeks injunctive relief, it need not demonstrate actual injury to establish a Lanham Act violation occurred here.

The undisputed evidence demonstrates that Healthport's statements concerning the ELG monitor and Mr. Wooten's credentials violate the Lanham Act. Healthport's motion for summary judgement on this issue should be denied. As a result, Tanita's motion for summary judgment should be granted. Tanita's request for an injunction permanently prohibiting Healthport from disseminating the false statements should likewise be granted. *See*15 U.S.C. § 1116(a).

3. Other Relief Requested

In addition to injunctive relief prohibiting future dissemination of the false statements, Tanita seeks corrective advertising, disgorgement of Healthport's profits, and attorneys fees. A plaintiff who establishes "a violation under section 43(a)" of the Lanham Act can recover the defendant's profits "subject to the principles of equity."15 U.S.C. § 1117(a). In addition, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party."*Id.*

"An inability to show actual damages does not alone preclude a recovery" under the Lanham Act. *Lindy Pen Co. v. Bic Pen Corp.*, 982 F.2d 1400, 1411 (9th Cir.1993)."The preferred approach allows the district court in its discretion to fashion relief, including monetary relief, based on the totality of the circumstances."*Southland Sod Farms*, 108 F.3d at 1146. Those circumstances include "the nature of the infringing actions, including the intent with which they were motivated and the actuality, if any, of their adverse effects upon the aggrieved party."*Lindy Pen Co.*, 982 F.2d at 1405.

a. The Defendant's Profits

***8** A plaintiff who seeks the defendant's profits as a measure of the plaintiff's own damages need not prove that the defendant's conduct was willful. *Adray v. Adry-Mart, Inc.*, 76 F.3d 984, 988 (9th Cir.1995) (citing *Lindy Pen Co.*, 982 F.2d at 1407-09). In those situations, lost profits serve as "surrogate measures of damages." *Harper*, 889 F.2d at 209 n. 8. Moreover, when an advertisement draws a direct comparison between the competitor's product and the plaintiff's, a court may presume injury because "[a] misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer."*McNeilab, Inc. v. Am. Home Products Corp.*, 848 F.2d 34, 38 (2nd Cir.1988); *see also Southland Sod Farms*, 108 F.3d at 1146;*Harper*, 889 F.2d at 209 n. 8. Where an advertisement does not draw a direct comparison, however, the plaintiff must present evidence of an injury "causally related to the defendant's deception."*Harper*, 889 F.2d at 209-210;*see also Lindy Pen Co.*, 982 F.2d at 1407-1409 (plaintiff must prove both the fact and amount of damages).

Alternately, a plaintiff can recover an accounting of the defendant's profits under a theory of unjust enrichment. *See Maier Brewing Co. v. Fleishmann Distilling Corp.*, 390 F.2d 117, 121 (9th Cir.1968). The court must consider whether an award of profits is necessary to remove the economic incentive to violate the Lanham Act. *See Polo Fashions, Inc. v.*

Dick Bruhn, Inc., 793 F.2d 1132, (9th Cir.1986) (plaintiff injured by defendant's deliberate sale of counterfeit products); *Playboy Enterprises, Inc. v. Baccarat Clothing Co.*, 692 F.2d 1272, 1274 (9th Cir.1982) (plaintiff injured by defendant's deliberate manufacture and sale of counterfeit products); *Maier Brewing Co.*, 390 F.2d at 121 (plaintiff injured by defendant's deliberate use of plaintiffs mark). The Ninth Circuit "has cautioned that an accounting is proper only where the defendant is 'attempting to gain the value of an established name of another.'"*Lindy Pen Co.*, 982 F.2d at 1406 (citing *Maier Brewing Co.*, 390 F.2d at 123). Thus, a willful violation may support an award of profits to the plaintiff but does not require one. *Faberge, Inc. v. Saxony Products, Inc.*, 605 F.2d 426, 429 (9th Cir.1979) (defendant's trade dress infringement sufficiently deterred by the costs of litigation and of modifying product packaging).

Here, the totality of the circumstances does not warrant an award of lost profits damages to Tanita. Assuming this remedy applies to false advertising claims, Tanita has provided no evidence that Healthport profited from its misrepresentations. *See Playboy Enterprises, Inc.*, 692 F.2d at 1276 (equity-based accounting of profits not appropriate if premised on "potentially fictitious sales from which the defendant derived no economic gain"). Thus, Tanita has not demonstrated that it suffered any actual harm or that Healthport derived any actual benefit that would justify the monetary relief Tanita seeks. Tanita's motion for summary judgment on lost profits damages should therefore be denied.

b. Corrective Advertising

***9** Corrective advertising may be appropriate to remedy consumer confusion caused by false advertising messages. *See Rhone-Poulend Rorer Pharmaceuticals, Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 516 (1996) (corrective advertising appropriate where advertisements falsely represented that two prescription medications could be indiscriminately substituted); *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 720 F.Supp. 194, 199-200 216 (D.D.C.1989) (corrective advertising ordered where extensive ad campaign falsely claimed that dog food effective in preventing canine hip dysplasia) *aff'd in part and vacated in part, remanded*913 F.2d 958;*see also Warner-Lambert Co. v. FTC*, 562 F.2d 749, 771 (1977) (corrective advertising did not violate the First Amendment where ad campaign falsely led consumers to believe product could cure common cold).

Tanita has requested that this Court order Healthport to post corrective advertising on all of Healthport's websites and to send corrective advertising to all of Healthport's "past and/or existing clients." Tanita. however, has presented no evidence that a large audience actually viewed the site or that consumers were and continue to be actually deceived about the nature of Healthport's products. As a result, this Court finds that corrective advertising is not necessary. *See Adray*, 76 F.3d 984 at 989 (damages for costs of prospective corrective advertising should not exceed the damage to the value of trademark). Tanita's request for corrective advertising should therefore be denied.

c. Attorneys Fees

Under 15 U.S.C. § 1117(a), a court may award reasonable attorneys' fees to the prevailing party in exceptional circumstances, which includes cases in which the act is fraudulent, deliberate, or willful. *See Gracie v. Gracie*, 217 F.3d 1060, 1068 (9th Cir.2000). A finding that the defendant acted intentionally "does not necessarily equate" with the malicious, fraudulent, deliberate or willful conduct. *See Watec Co., Ltd. v. Liu*, 403 F.3d 645, 656 (9th Cir.2005). Thus, sufficient **undisputed evidence must demonstrate that** the defendant deliberately intended to deceive consumers. *See Earthquake Sound Corp. v. Bumper Indus.*, 352 F.3d 1210, 1217-18 (9th Cir.2003).

Here, Healthport's liability rests on a presumption of consumer deception and reliance. This Court recognizes that Healthport intentionally made a false statement concerning Mr. Wooten's credentials. However, this statement is only marginally material to consumer purchasing decisions. While the statement regarding ELG accuracy bears more relevance to consumer decisions, the evidence does not demonstrate that Healthport engaged in a concerted effort to deceive consumers sufficient to justify an award of attorneys fees. As a result, Tanita's request for attorney's fees should be denied.

CONCLUSION

I recommend denying Healthport's motion for summary judgment (# 100), and granting Tanita's motion for summary judgment (# 99). I recommend that an injunctive order be entered requiring Healthport to immediately remove the ELG and Wooten misrepresentations from its web sites, and which forever prohibits Healthport from publishing any advertising or promotional material that contains representations to the effect that the ELG: (1) is the only patented body composition analyzer or metabolic analyzer in the United States or abroad; (2) is patented for unequaled accuracy and validity; (3) is the only body composition analyzer or metabolic analyzer patented for unequaled accuracy and validity; (4) is unequaled in accuracy and validity as compared to other body composition analyzers. I also recommend that an injunctive order be entered that forever prohibits Healthport from publishing any advertising or promotional material which falsely represents the credentials of Richard Wooten or other principals and employees of Healthport.

***10** Finally, in light of Tanita's indication that its common law unfair competition claim will rise and fall with its Lanham Act claim, this ruling on the parties' cross-motions for summary judgment resolves all the claims in this case. Judgment should be entered accordingly.

SCHEDULING ORDER

The above Findings and Recommendation will be referred to a United States District Judge for review. Objections, if any, are due April 23, 2008. If no objections are filed, review of the Findings and Recommendation will go under advisement on that date. If objections are filed, a response to the objections is due fourteen days after the date the objections are filed and the review of the Findings and Recommendation will go under advisement on that date.

FN1. As part of this decision, defendant's other pending objection [106] is overruled.

FN1. Tanita filed an Amended Answer and Counterclaims on February 13, 2008, which abandoned its request for money damages.

FN2. Tanita did not move for summary judgment on its common law unfair competition claim. At oral argument, however, Tanita indicated that its unfair competition claim rises and falls with its Lanham Act claim.

FN3. www.cybercareplan.md/what.htm

FN4. www.healthechanges.com/benefits.cqs

FN5. Although Healthport asserted that the CyberCare site contained a login page, testimony by Mr. Wooten and Dr. Libke indicated otherwise and this Court was able to access both sites without a login or password. This Court finds that the question of the existence of a login page is not a disputed material fact. "The opposing party may not rely on denials in the pleadings but must produce specific evidence, through affidavits or admissible discovery material, to show that the dispute exists."*Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d 262, 265 (9th Cir.1991).

FN6. Healthport presented no facts concerning the Health-e-Changes site. However, Dr. Libke's deposition testimony indicated that the Health-e-Changes and CyberCare Plan sites had similar content and served a similar purpose.

D.Or.,2008.
Healthport Corp. v. Tanita Corp. of America
--- F.Supp.2d ----, 2008 WL 2224398 (D.Or.)

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APPENDIX 4

Midwest Canvas Corp. v. Commonwealth Canvas, Inc.
N.D.Ill.,2008.
Only the Westlaw citation is currently available.
United States District Court,N.D. Illinois,Eastern Division.
MIDWEST CANVAS CORP., an Illinois Corporation, Plaintiff,
v.
COMMONWEALTH CANVAS, INC., a Massachusetts Corp., et al., Defendants.
No. 07 C 0085.

Jan. 16, 2008.

Jennifer Ann Esposito, Kantor & Apter, Ltd., David G. Rosenbaum, John Peter Paredes, Rosenbaum And Associates, P.C., Northbrook, IL, for Plaintiff.
Jan M. Michaels, John A. Lee, Steven Schulwolf, Michaels & May, P.C., Robert A. Habib, Attorney at Law, Peter Carl Nabhani, Law Office of Peter Nabhani, Stephen Andrew Skardon, Chicago, IL, for Defendants.

MEMORANDUM OPINION AND ORDER

JOAN B. GOTTSCHALL, District Judge.
***1** Plaintiff Midwest Canvas Corp. ("Midwest") has filed suit against defendants Commonwealth Canvas, Inc. ("Commonwealth"), Raw Equipment Corporation ("Raw"), and Constructioncomplete.com ("CC.com") alleging, *inter alia*, violations by Commonwealth and Raw of the Lanham Act, 15 U.S.C. § 1125(a) (Count V); the Uniform Trade Deceptive Practices Act, 815 ILCS 510/1 (Count VI); and state common law unfair competition (Count VII); and violation by Commonwealth and CC.com of the Lanham Act (Count VIII); the Uniform Trade Deceptive Practices Act (Count IX); and state common law unfair competition (Count X). Before the court is Commonwealth's motion to dismiss Counts V-X and Raw's motion to dismiss Counts V-VII. For the reasons set forth below, Commonwealth's and Raw's motions to dismiss are granted.

I. BACKGROUND

Midwest and Commonwealth are competing corporations engaged in the manufacture of, among other items, concrete curing blankets. Pl .'s First Amended Compl. ¶¶ 1-2. Concrete curing blankets are employed to cover freshly poured concrete. The blanket protects the surface of the concrete and its insulating qualities trap the heat released as the concrete cures and thus accelerates the hardening process; this is particularly important during construction in cold weather. Raw is a corporation engaged in the marketing and distribution of Commonwealth's products, including its curing blankets. Pl.'s First Amended Compl. ¶¶ 3-4.

One of Commonwealth's curing blankets, with the trade name "Cure-All," is listed on the website of the New York Department of Transportation ("NYDOT") on the page presenting the "Technical Services-Materials-Approved List" of form insulation materials for winter concreting (Form 711-07). Pl.'s First Amended Compl. ¶¶ 40-41; *see also* h ttps://www.nysdot.gov/portal/page/portal/divisions/engineering/technicalservices/technical-services-repository/alme/pages/310-1.html (last visited Jan. 8, 2008). Commonwealth's blanket is one of seventeen curing blankets manufactured by eleven different corporations (including two of Midwest's "Insul-Tarp" products) that are listed as approved for use in NYDOT construction projects. *Id.;* Pl.'s First Amended Comp. Exh. C. The NYDOT website lists the Commonwealth "Cure-All" blanket as having a thickness of 25 mm (1). Pl.'s First Amended Compl. ¶ 42. No pricing or direct ordering information are listed on the website. Pl.'s First Amended Comp. Exh. C.

In April 2007, after the initial complaint in this suit was filed [FN1], Tim Dunphy ("Dunphy"), who was employed as a sales manager by Midwest, placed an order with Raw for a 25 mm "Cure-All" curing blanket, the same as listed on the NYDOT website. Pl.'s First Amended Compl. ¶ ¶ 43-44. Raw duly delivered a curing blanket, together with an invoice describing it as a "CLOSED CELL 1 NYSDOT CURING BLANKETS (sic) 6'x 25'."Pl.'s First Amended Compl. ¶¶ 45-46, Exh. D. Midwest claims that Dunphy, upon inspecting the curing blanket

received from Raw, discovered that it was not 25 mm in thickness. Pl.'s First Amended Compl. ¶¶ 47-48.

> FN1. The initial complaint in this suit was filed on January 8, 2007. Midwest filed its amended complaint on June 28, 2007.

***2** Previously, in February 2007, Dunphy had likewise ordered a 1/2 (CC2) and 1 ("CC4") curing blankets from CC.com, which advertises and sells Commonwealth curing blankets. Pl.'s First Amended Compl. ¶¶ 62-65, Exh. E. The order was confirmed via email and, later, two curing blankets, together with a work order describing the blankets as being "CC2 6x25 2 LAYER FOAM CONCRETE CURING BLANKET" and "MISC CC-2 4 LAYER FOAM CONCRETE CURING BLANKET," were received by Midwest. Pl.'s First Amended Compl. ¶¶ 66-68, Exhs. F-G. Midwest claims that the received blankets were not 1/2 and 1 respectively in thickness. Pl.'s First Amended Compl. ¶ 69.

Count V of Midwest's first amended complaint claims that the invoice accompanying the curing blanket received from Raw constitutes commercial advertising as defined by the Lanham Act, 15 U.S.C. § 1125(a), and that Raw's provision of a curing blanket that was not 25 mm in thickness thereby constituted materially false and misleading representations about the nature and quality of the curing blanket. Counts VI and VII are pendant state and common law claims that Raw's actions respectively constituted a violation of the Illinois Uniform Trade Practices Act, 815 ILCS 510/1 et seq. and "New York and other state common law unfair competition."

Similarly, Count VIII of Midwest's amended complaint claims that the work order received with the blankets from CC.com constitutes false advertising in violation of the Lanham Act and that Commonwealth and CC.com's actions in selling the blankets are misleading and false. Counts IX and X claim respectively violations of the Illinois Uniform Trade Practices Act, 815 ILCS 510/1 et seq., and unfair competition under Illinois common law. Commonwealth has filed a motion to dismiss Counts V-X under Federal Rule of Civil Procedure 12(b)(6) and Raw has filed a motion to dismiss Counts V-VII on the same theory. Raw has also moved to dismiss the amended complaint under Federal Rule of Civil Procedure 9(b), alleging that Midwest has failed to plead fraud with the required particularity. Because the issues in both motions are essentially identical, the court considers both of these motions together.

II. ANALYSIS

To survive a motion to dismiss under 12(b)(6), "the complaint need only contain a 'short and plain statement of the claim showing that the pleader is entitled to relief.' " *Equal Opportunity Comm'n v. Concentra Health Servs., Inc.*, 496 F.3d 773, 776 (7th Cir.2007) (quoting Fed.R.Civ.P. 8(a)(2)). The complaint "must describe the claim in sufficient detail to give the defendant 'fair notice of what the ... claim is and the grounds upon which it rests' ... [and] its allegations must plausibly suggest that the plaintiff has a right to relief, raising that possibility above a 'speculative level'; if they do not, the plaintiff pleads itself out of court." *Concentra*, 496 F.3d at 776 (quoting *Bell Atlantic Corp. v. Twombly*, --- U.S. ----, 127 S.Ct. 1955, 1964, 1973 n. 14, 167 L.Ed.2d 929 (2007)).

A. Midwest's Counts V-VII

***3** Count V claims specifically that the invoice accompanying Raw's shipment of the blanket to Midwest constituted advertising under the Lanham Act, and that Commonwealth and Raw's collective actions of selling blankets that are purported to be 1 thick but are not constitute material false and misleading misrepresentations about the nature of Commonwealth's products.

The Lanham Act (§ 43(a)) provides in relevant part that any person who: "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act."15 U .S.C. § 1125(a)(1)(B). To establish a claim under the false or deceptive advertising prong of § 43(a) of the Lanham Act, a plaintiff must prove: (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the

defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a loss of goodwill associated with its products. *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir.1999); *The Monotype Corp. v. Simon & Schuster, Inc.*, No. 99 C 4128, 2000 WL 1852907, at *6 (N.D.Ill. Sept.8, 2000).

Midwest specifically claims that the invoice accompanying the allegedly misrepresented curing blanket constitutes false commercial advertising under the Lanham Act. For a statement to amount to "commercial advertising or promotion" the statements must be (1) commercial speech (2) by a defendant who is in commercial competition with the plaintiff (3) for the purpose of inducing consumers to buy defendant's goods or services (4) disseminated sufficiently to the relevant purchasing public. *Health Care Compare Corp. v. United Payors and United Providers, Inc.*, No. 96 C 2518, 1998 WL 122900 at *3 (N.D.Ill. Mar.13, 1998).

The court finds that Midwest's argument that the invoice accompanying Raw's delivered curing blanket constitutes advertising fails to meet these criteria. An invoice sent to an individual customer and accompanying an order can hardly be construed to have been "disseminated sufficiently to the relevant purchasing public" because it lacks the element of publicity required by the Lanham Act.*American Needle & Novelty, Inc. v. Drew Pearson Marketing, Inc.*, 820 F.Supp. 1072, 1078 (N.D.Ill.1993) (Lanham Act's use of the terms "advertising" or "promotion" have requisite element of publicity); *see also Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194, 105 S.Ct. 658, 83 L.Ed.2d 582 (1985) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."). An invoice accompanying an order shipped to an individual customer lacks the requisite element of publicity. It is true, as Midwest points out correctly, that the required level of circulation establishing publicity will vary according to the specifics of each industry and can be so small as to comprise a single party. *Seven-up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1385 (5th Cir.1996). Nevertheless, even if a presentation to a single individual could possibly be considered public enough to satisfy publicity requirement of the statute, an invoice cannot be advertising because it is not an inducement to buy, but rather reflects an agreed-upon transaction.

***4** Specifically, an invoice accompanying an order shipped to a client is not sent for the "purpose of inducing consumers to buy defendant's goods or services"; the goods accompanying a shipment have already been ordered by the consumer who needs no further inducement to buy them. In sum, a single private communication from one party to another that is not an inducement to buy does not constitute commercial advertising sufficient to establish liability under the Lanham Act. *See American Needle*, 820 F.Supp. at 1078.

In its response to Commonwealth's and Raw's motions to dismiss, Midwest argues that the fourth prong is also satisfied because Commonwealth caused its products to become listed by NYDOT on NYDOT's website, and also because Commonwealth allegedly employed distributors who disseminated the "defendant's" (presumably Commonwealth's) statements over the internet in connection with promoting the sale of 1 NYDOT approved concrete curing blankets. The specifics of this claim are not clearly alleged in Midwest's complaint, but the court will assume, *arguendo*, that this argument falls under the rubric of Midwest's allegations, stated in its complaint, that Commonwealth's and Raw's "misrepresentations constituting false advertising" resulted from their "actions of selling concrete curing blankets that are purported to be 1 blankets when they are not ...." Pl.'s First Amended Compl. ¶¶ 50-52

To begin with, Midwest's claims on this point fall far short of the particularity required by Federal Rule of Civil Procedure 9(b) for pleadings alleging fraud. When alleging claims of fraud or mistake, the plaintiff is required to plead with specificity the who, the what, the where, and the when of the alleged fraud. FED R. CIV. P. 9(b); *Fidelity Nat. Title Ins. Co. of New York v. Intercounty Nat. Title Ins.*, 412 F.3d 745, 749 (7th Cir.2005). In Count V, Midwest vaguely alleges that the listing of the Commonwealth blanket on the NYDOT site, and Commonwealth's and Raw's alleged misrepresentations, are somehow connected in such a way as to create a fraudulent advertisement in violation of the Lanham Act. But

Midwest fails to allege with particularity just what, if any, the connection between the NYDOT website and Raw is. Not does it aver with any particularity what allegedly false statements have been made by Commonwealth or Raw other than the invoice; and the court has already determined that the invoice is not a commercial advertisement. Moreover, it does not allege with sufficient particularity a causal connection between Commonwealth's listing of its product on the NYDOT website and any direct or indirect misrepresentation whatever by Commonwealth to Midwest.

Even placing the issue of particularity aside, the listing of Commonwealth's (and Midwest's) curing blankets on the NYDOT website cannot be construed as a commercial advertisement by Commonwealth because the actual maker of the statement, NYDOT, a state government entity, is not in direct commercial competition with any of the companies whose curing blankets are listed on its Website, including Commonwealth and Midwest. Therefore, the listing cannot be a commercial advertisement or promotion by which liability can be established under § 43(a) of the Lanham Act. *Health Care Compare*, 1998 WL 122900 at *3.

***5** Furthermore, the NYDOT website listing of approved construction materials, including curing blankets, is not an inducement to the public to buy Commonwealth's (or any of the other manufacturer's) products. The listing of approved materials on the NYDOT website is presented as part of a "quality assurance program for materials incorporated into [NYDOT] projects ...."*See* https://www.nysdot.gov/portal/page/portal/divisions/engineering/technicalservices/materials-bureau/materials-and-equipment (last visited Jan. 8, 2008). In short, the website lists materials approved for use by NYDOT and its contractors in carrying out NYDOT projects. It is just possible, arguably, that such a listing could have mixed commercial and non-commercial components-identifying blankets suitable for NYDOT purposes as well as supporting preferred vendors. The key to determining whether such a listing might qualify as commercial advertising for Lanham Act purposes is an analysis of whether the language is motivated primarily by commercial concerns, or whether there are sufficient non-commercial motivations. *Monotype*, 2000 WL 1852907, at *7:*Oxycal Lab., Inc. v. Jeffers*, 909 F.Supp. 719, 725 (S.D.Cal.1995). Under this analysis, the listing of approved materials cannot be construed as commercial advertising: its principal purpose is to ensure that approved materials of sufficient quality are employed by NYDOT and its contractors in its construction projects. Such a purpose is most reasonably interpreted as being motivated by both quality assurance and public safety concerns. Because the principal purpose of the listing is informational, rather than commercial, it is not commercial advertising, and Midwest's claim fails. *Monotype*, 2000 WL 1852907, at *7.

Finally, Counts VI and VII allege the same factual elements as Count V. The same analysis employed in determining whether a claim for false or deceptive advertising exists under the Lanham Act is employed for Illinois false advertising claims. *Muzikowski v. Paramount Pictures Corp.*, 477 F.3d 899, 907 (7th Cir.2007); *Peaceable Planet, Inc. v. Ty, Inc.*, 362 F.3d 986, 994 (7th Cir.2004). Therefore, for the same reasons presented above, Counts VI and VII also fail to state a claim upon which relief can be granted under the Illinois Uniform Trade Practices Act, 815 ILCS 510/1 et seq., and state common law unfair competition.[FN2]Midwest's Counts V through VII against Commonwealth and Raw are consequently dismissed.

FN2. Count VII alleges violations by Raw of "New York and other state common law unfair competition," whereas Count X alleges "unfair competition, deceptive advertising and unfair trade practices under Illinois common law. (Confusingly, Counts VI and IX allege violation of the Illinois Uniform Trade Deceptive Trade Practices Act, 815 ILCS 510/1 *et seq.*). Federal courts sitting in Illinois employ Illinois state choice of law rules. *Gramercy Mills, Inc. v. Wolens*, 63 F.3d 569, 572 (7th Cir.1995). However, the choice of law issue confronting the court is moot in this instance, because the elements of both New York and Illinois unfair competition common law are very similar or identical to the Lanham Act and the legal analysis is substantially the same. *See, e.g., Paco Sport, Ltd. v. Paco Rabanne Perfumes*, 234 F.3d 1262, 1262 (2d Cir.2000); *Muzikowski v. Paramount Pictures Corp.*, 477 F.3d 899, 907 (7th

Cir.2007). Under either Illinois or New York unfair competition common law, Midwest's Count VIII must be dismissed.

B. Midwest's Counts VIII-X

Midwest's Counts VIII through X against Commonwealth and CC.com have the same weaknesses as do Counts V through VII of their amended complaint against Commonwealth and Raw. Midwest's argument that the "work order" accompanying its order of two curing blankets from CC .com fails because a work order cannot be construed as commercial advertising by the court for the same reason that an invoice cannot be: it fails to meet the required elements of inducement of the public to buy and publicity. *See American Needle*, 820 F.Supp. at 1078. Midwest's implied claim that Commonwealth is somehow responsible for the representations on CC.com's website (which are presented as exhibits but not alleged as constituting false advertising in Counts VIII-X complaint) is not made with sufficient particularity to satisfy the requirements of Federal Rule of Civil Procedure 9(b).[FN3] Moreover, for the same reasons as listed above, because Count VIII fails to state a claim upon which relief can be granted under the Lanham Act, the Illinois statutory and common law claims of Counts IX and X also fail and Commonwealth's motion to dismiss these Counts is also granted.

FN3. Defendant CC.com has not yet filed an answer to Midwest's complaint and so this order will not consider CC.com's role in this suit.

III. CONCLUSION

***6** For the reasons listed above, Commonwealth's motion to dismiss Counts V-X and Raw's motion to dismiss Counts V-VII of Midwest's first amended complaint are granted.

N.D.Ill.,2008.
Midwest Canvas Corp. v. Commonwealth Canvas, Inc.
Slip Copy, 2008 WL 162757 (N.D.Ill.)

END OF DOCUMENT

APPENDIX 5

H

Patient Transfer Systems, Inc. v. Patient Handling Solutions, Inc.
E.D.Pa.,2001.
Only the Westlaw citation is currently available.
United States District Court, E.D. Pennsylvania.
PATIENT TRANSFER SYSTEMS, INC., Plaintiff,
v.
PATIENT HANDLING SOLUTIONS, INC., D.T. Davis Enterprises, Ltd., David T. Davis, and Joanne S. Davis, Defendants.
No. CIV.A. 97-1568.

Aug. 16, 2001.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

YOHN, J.

***1** Patent Transfer Systems, Inc. [“PTS”] sued David T. Davis, Patient Handling Solutions, Inc. [“PHSI”], and D.T. Davis Enterprises, Ltd. [collectively, “defendants”] for infringing on patent number 5,561,873 [“ '873 patent”], false advertising, breach of fiduciary duty, conversion of corporate assets, and misappropriation of trade secrets.FN1PTS manufactures and sells air inflatable mattress pads that are used to support and move patients in hospitals and other health care facilities.FN2PTS employed Davis until November 1994. Sometime after Davis left PTS, he incorporated PHSI, a business that competed with PTS as a manufacturer and seller of air inflatable mattress pads. This lawsuit resulted.

FN1. PTS has stipulated to the dismissal of claims against Joanne S. Davis. *See* Pl.'s Pre-Trial Mem. 1 (Doc. No. 138). Furthermore, the parties stipulated to the dismissal of PTS's claim for copyright infringement and Davis's counterclaim for tortious interference with prospective contractual relations. *See* Pl.'s Trial Mem. on the Legal Issues Involved in the Case (Doc. No. 145/146).

FN2. In this opinion, I will generally refer to this type of product as an “air transfer mattress.”

The trial on damages has been bifurcated from the trial of liability. *See* Order of May 19, 1998 (Doc. No. 80). Having considered both parties' pre- and post-trial filings as well as all of the testimony and exhibits offered at trial on the issue of liability, I now, pursuant to Fed.R.Civ.P. 52(a), make the following findings of fact and conclusions of law:

I. Findings of Fact

A. Background

1. History of the Air Transfer Mattress

a. General Description of an Air Transfer Mattress

(1) An air transfer mattress is an inflatable pad composed of a series of interconnected inflatable chambers that is primarily used to move patients in hospitals and in emergency rescue situations from one horizontal surface to another. The surface of the bottom of the mattress has a pattern of small, closely spaced pinholes that allow air to escape from the mattress. This air forms an air bearing “lift” under the weight of the patient that reduces the exertion necessary to move a patient and, as a result, the risk of injury to the individual(s) moving the patient. *See* Joint Findings of Fact and Conclusions of Law [“JFF”] ¶ 5 (Doc. No. 140).

b. Early Air Transfer Technology

(1) Raynor Johnson and another individual patented an air-bearing pallet for moving heavy cartons (U.S. 3,948,344).*See* JFF ¶ 7.

(2) Johnson incorporated American Industrial Research, Inc. [“A.I.R.”]. *See* JFF ¶ 7.

(3) Jack Wegener became associated with A.I.R., and Johnson and Wegener decided to develop and market an air transfer pad. *See* JFF ¶ 7.

(4) Using a concept similar to the air-bearing pallet Johnson invented, Wegener patented an air pallet for use in a hospital setting, patent number 4,272,856. *See* JFF ¶ 7.

c. The A.I.R. PAL “Hard Pad”

(1) The air-bearing pallet Wegener patented utilized a rigid insert to keep the pad level during inflation and to provide stable support for the load. As a result, the air-bearing pallet was referred to as a “hard pad.” *See* JFF ¶ 9.

(2) A.I.R. decided to develop the air-bearing pallet technology to make air transfer devices for moving human beings. *See* JFF ¶ 7.

(3) Johnson and Wegener presented their business plan to Robert E. Weedling and asked him to join their venture. *See* JFF ¶ 7.

***2** (4) Weedling incorporated LCI Medical, Inc. to develop and market air transfer devices that would be used to move patients. *See* JFF ¶ 8.

(5) IN 1984, LCI Medical began manufacturing the pallet as a transfer pad mover for patients and began shipping these “hard pad” patient movers under the A.I.R. PAL trademark it licensed from A.I.R. *See* JFF ¶ 9.

d. Development of “Soft Pads”

(1) The size and bulk of these “hard pad” patient movers made them difficult to store. *See* JFF ¶¶ 9-10. As a result, from 1986 to 1990, LCI Medical, Wegener, and Johnson attempted to develop a patient transfer pad that did not require a rigid insert. *See* JFF ¶ 10.

(2) These development efforts resulted in two designs of a flexible “soft pad.” *See* JFF ¶ 10.

e. The “Old Blue” Soft Pad

(1) The first “soft pad” was called “Old Blue” and it had a single layer of longitudinal (head-to-toe) air chambers. LCI Medical sold “Old Blue” soft pads in 1988 and 1989. *See* JFF ¶ 10.

f. The '189 Patent

(1) In 1988 or 1989, PTS retained patent attorney Donald E. Zinn to prepare a patent application for a second “soft pad.” Zinn met with Wegener, Johnson, Weedling, and William Swallen at Johnson's A.I.R. facility in Newark, Delaware to discuss this purported invention. *See* Weedling Direct Testimony (Jan. 22, 2001); Cross Examination of Swallen (Jan. 24, 2001); DX-84 (Zinn Deposition) at 6. Ultimately, the second “soft pad” became the subject matter of the 1990 patent application that became patent number 5,067,189 [“ '189 patent”].*See* JFF ¶ 11.

(2) The '189 Patent named Weedling, Swallen, Johnson, Wegener, and Davis as co-inventors. However, Davis and Swallen assigned their interests in the patent to Weedling. *See* JFF ¶ 11.

(3) The pads described in the '189 patent were first shipped in late 1989 and they replaced the “Old Blue” as LCI Medical's “soft pad.” *See* JFF ¶ 11.

(4) In 1993, Weedling retained Sanford J. Piltch, Esq. as a patent attorney to review the '189 patent with the inventors. As a result of that review, in November 1993, Piltch filed an application for a broadening re-issue of the '189 patent (Patent No. RE 235,299). In July 1996, the Patent Office examined the patent and re-issued it with broader claims covering lateral chambers. *See* JFF ¶ 13.

g. The '873 Patent

(1) Between approximately May 1993 to October 1994, the current air transfer mattress was designed at PTS. *See* JFF ¶ 14.

(2) The current air transfer mattress was designed to eliminate the instability of the older air pads. *See* JFF ¶ 15.

(3) The current design also features offset partitions so that, when the mattress is deflated, the partitions lie down flat. This feature eliminated the folds of the older air pads that caused patient discomfort. *See* JFF ¶ 16.

(4) During the design process, PTS received a request from the Mayo Clinic for an oversized pad to transfer an obese patient. As a result of this request, an oversized pad was constructed with a longitudinal (head-to-toe) partition along each side to add stability. Holes were placed in the longitudinal stringers to facilitate air flow into the lateral air chambers. On January 6, 1994, the oversized pad was sent to the Mayo Clinic. *See* JFF ¶ 17.

***3** (5) After discussions with Piltch, the application for the current design of the air mattress, which became the '873 patent, was filed on July 15, 1994. The patent application listed Weedling and Davis as co-inventors. *See* JFF ¶ 18-19.

2. Weedling's Employment History

a. Weedling founded Lehigh Valley Packing in 1975. In 1980, Weedling changed the name of Lehigh Valley Packing to Lehigh Consolidated Industries (LCI).*See* JFF ¶ 6.

b. In 1984, Weedling incorporated LCI Medical. *See* JFF ¶ 8.

c. In 1992, Weedling filed for bankruptcy and LCI Medical went out of business. *See* JFF ¶ 12.

d. In August 1992, Weedling incorporated PTS, and he has been the president and majority shareholder of PTS since that time. *See* JFF ¶ 1.

e. PTS is a Pennsylvania corporation that manufactures and sells air transfer mattresses. *See* JFF ¶ 1.

3. Davis's Employment History

a. Davis was employed by LCI from 1982 to 1984. *See* JFF ¶ 20.

b. In 1984, Davis became an employee of LCI Medical.

c. At LCI Medical, Davis supervised the manufacture of the air transfer pads. Davis also made regular sales calls to customers and potential customers, provided demonstrations of the A.I.R. PAL, and trained customers to use the A.I.R. PAL. Davis also maintained LCI Medical's parts inventory. As a result, Davis had access to LCI Medical's manufacturing records, research files, vendor lists, and user lists. *See* JFF ¶ 21.

d. In 1992, Davis was appointed a Vice President of Sales at LCI Medical. *See* JFF ¶ 20.

e. In August 1992, Davis became the Vice President of Sales of PTS. At the time, Davis was the only full-time employee of PTS. *See* JFF ¶ 20.

f. While he was employed by PTS, Davis was an "at will" employee. Davis did not have a written employment agreement or any confidentiality or secrecy agreement or covenant not to compete with PTS. Davis was also not a shareholder of PTS. *See* JFF ¶ 20.

g. In 1993, PTS moved into an industrial warehouse in Allentown, Pennsylvania with another company incorporated by Weedling, Gateway Industrial Services, Inc.

h. As noted above, the patent application for the current design of the air transfer mattress, which became the '873 patent, listed Weedling and Davis as co-inventors. *See* JFF ¶ 18-19.

i. At some point thereafter, Weedling asked Davis to assign his interest in the patent to PTS. Davis

considered Weedling's request but, ultimately, in November 1994, he refused to transfer his interest in the patent. *See* JFF ¶ .

j. In September 1994, Davis met with the owner of Ryan Medical, Inc., Roger Parking. On October 19, 1994, Davis agreed not to disclose to any other party a proposed business transaction between Ryan Medical and Davis. *See* JFF ¶ 28.

***4** k. On November 14, 1994. Davis resigned from his job at PTS. *See* JFF ¶ 22.

l. In December 1994, Davis became an employee of Ryan Medical. Davis was hired by Ryan Medical to sell patient lift devices and to begin to market an air transfer mattress. *See* JFF ¶ 30.

m. On December 22, 1994, Davis entered a written agreement with Ryan Medical to assign any rights he had in the patent application that later became the '873 patent to Roger Parkin. *See* JFF ¶ 31.

n. On January 27, 1995, Davis and Ryan Medical terminated his employment and their agreement by mutual consent. Davis paid Roger Parkin $9,486.50 for legal expenses and the nylon fabric purchased in November 1994 from Brookwood. *See* JFF ¶ 32.

o. In January 1995, Davis asked PTS's vendor for fabric perforation services, Perforating Industries, Inc., to fax him copies of the perforation drawing sheets that PTS had supplied to Perforating Industries. Perforating Industries faxed the drawings to Davis. *See* JFF ¶ 34.

p. In March 1995, Davis sent 300 yards of the nylon fabric that Ryan Medical purchased from Brookwood to Perforating Industries with instructions for the fabric to be perforated as described in one of the drawing sheets PTS had supplied to Perforating Industries. *See* JFF ¶ 35.

q. On June 27, 1995, Davis acquired a license to the '189 patent from Wegener. *See* JFF ¶ 36.

r. Davis purchased almost all of the materials, parts, and services for his air transfer mattresses from the same vendors used by PTS. *See* JFF ¶ 40.

s. In August 1995, Davis ordered air supply hoses from R/W Connection, PTS's former vendor for this component. R/W Connection addressed its invoice to PTS but sent the hoses to Davis's address. *See* JFF ¶ 41.

t. In 1995, Davis contacted PTS customers Carney Hospital, Crozer-Chester Hospital, Concord Hospital, Frankford Hospital, Sacred Heart Hospital, and the Medical Center of Delaware. *See* JFF ¶ 42.

u. In mid-1995, Davis made several air transfer mattresses and provided them to the Medical Center of Delaware for an evaluation. *See* JFF ¶ 39.

v. Davis initially marketed his air transfer mattresses under the name “AIR PAD.” In 1996, Davis changed the name to “TransPad.” In 1997, Davis changed the name to the present name, “HoverMatt.” *See* JFF ¶ 43.

w. Davis incorporated PHSI in August 1995. PHSI manufactured and sold inflatable air transfer mattresses until April 1997. *See* JFF ¶ 2.

x. Davis incorporated D.T. Davis Enterprises (DTD), Ltd. on May 8, 1997. DTD trades under the name Patient Handling Technologies, and it has manufactured and sold air transfer mattresses since May 1997. *See* JFF ¶ 4.

B. Patient Infringement [FN3]

> FN3. During closing arguments, PTS dropped its infringement claim as to the Air Pad, and defendants dropped their request to invalidate the '873 patent.

1. Weedling's Knowledge of the Standard for Inventorship

a. During a 1988 or 1989 meeting regarding the preparation of the '189 patent, Attorney Zinn told Weedling that the standard for inventorship is that

the individual must contribute to the novel aspect of at least one claim of the patent. *See* DX-84 (Zinn Deposition) at 5-8, 10, 12; Wegener Direct Testimony (Jan. 25, 2001).

***5** b. After being informed of this standard, Weedling told Attorney Zinn that Davis had made a contribution and should be named as an inventor in the '189 patent application. *See* Weedling Direct Testimony (Jan. 22, 2001); Wegener Direct Testimony (Jan. 25, 2001).

c. As noted above, Davis was also named as an inventor on the later '873 patent application.

2. Responsibility for Preparing Drawings

a. Weedling has limited drawing experience. *See* Weedling Direct Testimony (Jan. 22, 2001).

b. Davis has an associate degree in Civil Engineering and has taken drafting courses. *See* Cross Examination of Davis as a Hostile Witness (Jan. 24, 2001).

c. After Swallen retired, Davis was responsible for preparing drawings. *See* Weedling Direct Testimony (Jan. 22, 2001); Cross Examination of Weedling (Jan. 23, 2001); PX-11.

d. The drawings in PX-11 are not memorializations of tests. Instead, given Davis's level of knowledge about the drawings and the reasons for the adjustments that the drawings show, it is clear that Davis made these drawings to propose ideas to Weedling. *See* Davis Direct Testimony (Jan. 26, 2001).

3. Conception of the Claims in the '873 Patent

a. Swallen stated that development was a group effort. Cross Examination of Swallen (Jan. 24, 2001).

b. When he visited PTS, Wegener observed Davis contributing to discussions and presenting his own ideas. *See* Wegener Direct Testimony (Jan. 25, 2001).

c. Davis claims that he conceived of the following elements of claims in the '873 patent:

(1) "lateral partition members making a lateral chamber with an arcuate lower longitudinal partition member and also the varying height partition members in a lateral direction"; FN4

FN4. Davis later restated this conception as follows: "lateral partition members with varying heights along with the longitudinal partition members going from a smaller height at the foot end to a larger height under the middle section and the upper torso with apertures [in the longitudinal partition members to allow air to go] into the lateral chambers."*See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

(2) lateral array of chambers; and

(3) lateral chambers surrounded by a perimeter chamber.

See Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

d. Davis claims that he and Weedling jointly conceived of the offset between the top and bottom sheets. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

e. Davis explained his contributions to each of the various ideas incorporated in the '873 patent and seemed very knowledgeable about what he contributed to its design. *See generally* Davis Direct Testimony as a Hostile Witness (Jan. 23-24, 2001); Davis Direct Testimony (Jan. 26, 2001).

f. Davis reviewed the drawings which he prepared contemporaneously with the events and explained the purpose of each of the various changes as the air transfer mattress was developed which resulted in the '873 patent. Davis displayed superior knowledge of the '873 patent and air transfer mattress technology in general. His contemporaneous draw-

ings corroborated his testimony. It is undisputed that Davis did most of the work on the Mayo mattress which was the predecessor of the '873 patent. *See generally* Davis Direct Testimony as a Hostile Witness (Jan. 23-24, 2001); Davis Direct Testimony (Jan. 26, 2001).

g. Weedling's testimony on the conceptions of the '873 patent and air transfer mattress technology in general was markedly less confident than Davis's testimony. For example, Weedling used less detail in explaining the claims of the '873 patent and his explanations often appeared to mimic the idiosyncratic terminology Davis used to describe his conceptions. Furthermore, Weedling made a number of errors while he was discussing his supposed conceptions. Finally, Weedling used the term "we" throughout his explanation of the invention development process. *See*, *e.g.*, Weedling Rebuttal Testimony (Feb. 1, 2001).

***6** h. Lateral Chambers

(1) Swallen and Weedling worked with lateral tubes on a wheelchair pad during the late 1980s. *See* Weedling Direct Testimony (Jan. 22, 2001); Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

(2) Although, prior to the '873 patent, PTS had used lateral air chambers in a pad, that pad was not an air transfer mattress because it does not have air holes in the bottom sheet. Cross Examination of Davis (Feb. 1, 2001).

(3) Davis claims that he conceived of the use of lateral chambers in an air transfer mattress while trying to solve a stability problem. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).*See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

(4) Drawing No. 4 in PX-11 provides evidence that Davis conceived of an air transfer mattress with an array of lateral chambers. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

4. Deletion of Davis as a Named Inventor on the '873 Patent

a. Attorney Piltch did not undertake a substantial investigation into the inventorship claims of Davis and Weedling when the '873 patent application was prepared. *See* Cross Examination of Piltch (Jan. 25, 2001); DX-79.

b. In June 1995, at Weedling's request, Attorney Piltch prepared a request to delete Davis as an inventor of the '873 patent before Piltch withdrew as an attorney for Davis. *See* Cross Examination of Piltch (Jan. 25, 2001); DX-79.

c. Piltch sent the letter to Davis by which he withdrew from representing Davis on June 21, 1995. Piltch sent the application to the Patent Office requesting deletion of Davis as a named inventor on June 22, 1995. Piltch did not notify Davis that he was doing so, and he did not notify the Patent Office that he no longer represented Davis. Moreover, even after Davis later retained an attorney, Piltch did not advise that attorney of the deletion. The method used to delete Davis as a co-inventor, although apparently legal, suggests that PTS felt Davis had a strong claim as a co-inventor. *See* Cross Examination of Piltch (Jan. 24, 2001); DX-20; DX-21.

d. Counsel stipulated that there was no deceptive intent on the part of Davis with regard to his removal as a named inventor.

5. Longitudinally Extending Portions [FN5]

FN5. Plaintiff is relying solely on the visual inspection of the air transfer mattresses to determine the issue of whether a portion of the partition member extends more in the direction of the longitudinal axis than in the direction of the lateral or transverse axis. Although the plaintiff offered considerable testimony regarding the distance the partition members extend in the longitudinal direction, *see* Piltch Direct Testimony

(Jan. 24, 2001); Cross Examination of Piltch (Jan. 24, 2001), both parties later agreed that this testimony was irrelevant. Neither party measured the relevant angles, even after suggestion by the court. *See* Piltch Direct Testimony (Jan. 24, 2001); Cross Examination of Piltch (Jan. 24, 2001); Davis Direct Testimony (Jan. 26, 2001); Cross Examination of Davis (Feb. 1, 2001).

***7** a. Upon visual inspection of deflated and inflated TransPad and HoverMatt air transfer mattresses, it is clear that no portion of any of the partition members in these air transfer mattresses is both: 1) attached to the top and bottom sheets of the air transfer mattress, and 2) extends more in the direction of the longitudinal axis than in the direction of the lateral or transverse axis. *See;* DX-66 (Air Pad Serial No. 3125); DX-66A (HoverMatt Serial No. 5024); DX-66C (See-through mattress that approximates DX-66A & DX-85); DX-68A (Air Pad Serial No. 3005 that approximates early TransPad); DX-85 (Equivalent to HoverMatt Serial No. 5024); DX-86 (Early TransPad); PX-121 (Lateral partition member); Piltch Direct Testimony (Jan. 24, 2001); Cross Examination of Piltch (Jan. 24, 2001); Davis Direct Testimony (Jan. 26, 2001); Cross Examination of Davis (Feb. 1, 2001).

b. My finding is confirmed by the expert testimony of patent attorney Lewis F. Gould, Jr. In particular, Gould found that neither the TransPad nor the HoverMatt contains partition members that have longitudinally extending portions, and that, even if the partition members do have longitudinally extending portions, those portions are not attached to the top and bottom sheets of the air transfer mattress. *See* Gould Direct Testimony (Jan. 25, 2001); Cross Examination of Gould (Jan. 25, 2001); DX-70 (Gould's Expert Report).

C. False Advertising

1. Among the PTS correspondence found in Davis's possession in March 1997 were the following testimonial letters and evaluation reports concerning the A.I.R. PAL:

a. An April 19, 1993 letter written by Colin J. Brigham, the Loss Control Manager of EBI Industries, that reported cost savings at an unnamed 230-bed hospital due to the use of the A.I.R. PAL.

b. A letter written by Brian Sanders of Crozier Keystone that reports cost reductions at that hospital.

c. An April 23, 1990 report written by Christine Collins of the Medical Center of Delaware that describes the results of a study of the A.I.R. PAL.

d. A June 22, 1989 letter written by Catherine Hujdich of St. Francis Hospital.

e. An April 28, 1993 letter written by Harold Hardinger of the University of Maryland.

f. An August 14, 1989 letter written by Hardinger.

g. A letter from Mt. Diablo Hospital.

h. A report on a 1989 study of the effect A.I.R. PAL material had on x-rays.

i. The "infection resistance report" of Lehigh Valley Hospital.

See JFF 25.

1. PTS used reproductions of these letters and materials in its sales and marketing efforts. *See* JFF ¶ 26.

2. PTS owns federal trademark registration 2,369,632 for AIR PAL and design for use on inflatable patient transfer and therapy pads. *See* JFF ¶ 47.

4. During 1995 and 1996, Davis sent letters on PHSI stationary to prospective customers in which he enclosed copies of the above-mentioned testimonial letters and evaluation reports. Although Davis

removed any references to PTS in the testimonial letters and evaluation reports, his use of the letters and reports was misleading. *See* JFF ¶ 44.

5. Hardinger's Testimonial Letter

***8** a. While he was employed by PTS, Davis asked Hardinger, a Registered Nurse at the University of Maryland Shock Trauma Center, to write a letter about his experience with air transfer mattresses. *See* Hardinger Direct Testimony (Jan. 24, 2001).

b. After Davis left PTS, he notified Hardinger that he no longer worked for PTS. *See* Hardinger Direct Testimony (Jan. 24, 2001).*See also* DX-37.

c. Davis asked Hardinger to "update" the testimonial letters he had written to LCI Medical or PTS. Hardinger updated his letter on March 30, 1996. In the updated letter, Hardinger removed references to the "AIR PAL" and the letter noted that the air transfer system had been used for seven years. *See* JFF ¶ 45.

d. Hardinger was aware that the Air Pad, TransPad, and HoverMatt were not manufactured and sold by the same entity that manufactured and sold the Air Pal. *See* Hardinger Direct Testimony (Jan. 24, 2001).

e. After Davis left PTS, Hardinger preferred to continue dealing with Davis because he was not impressed by a demonstration conducted by Weedling. *See* Hardinger Direct Testimony (Jan. 24, 2001).

6. Brigham's Testimonial Letter

a. Davis asked Amos Brigham, a Safety and Health Consultant, if PHSI could use the results of the Sacred Heart Hospital study. Brigham gave his approval and updated his letter with one dated February 19, 1996. At Davis's request, Brigham addressed the updated letter to PHSI and replaced references to the "AIR PAL" with the phrase "patient/air transfer technology product." *See* JFF ¶ 45; Brigham Direct Testimony (Jan 25, 2001).

b. When Brigham approved these changes, he was aware that Davis no longer was working for PTS and that PHSI was a different entity. Brigham was also aware that the Air Pad, TransPad, and HoverMatt were not manufactured and sold by the same entity that manufactured and sold the Air Pal. *See* Brigham Direct Testimony (Jan 25, 2001).

c. Davis sent the updated Brigham letter to prospective customers. *See* JFF ¶ 45.

7. Sanders's Testimonial Letter

a. Davis asked Sanders to "update" the testimonial letters he had written to LCI Medical or PTS. Sanders updated his letter on January 16, 1997 and addressed it to Davis at PHSI, and again on June 24, 1997, this time addressing it to Davis at PHT. In both letters, Sanders replaced references to the "AIR PAL" with the phrase "Air/Transfer Technologic system." *See* JFF ¶ 45.

b. Davis sent the updated Sanders letter to prospective customers. *See* JFF ¶ 45.

8. Koury and the Acquisition of "Air Pals" from PHSI

a. After Davis left PTS, Steve Koury, the Clinical manager at Carney Hospital in Boston, was not impressed by a product demonstration conducted by Weedling. As a result, Koury preferred to continue dealing with Davis. *See* Koury Direct Testimony (Jan. 24, 2001).

b. In three price quote letters to Koury, Davis referred to his product as the "AIR PAL." On April 12, 1996, Carney Hospital ordered 17 "AIR PAL" mattresses and 5 "AIR PAL" blowers. On May 13, 1996, Carney Hospital ordered an additional 7 "AIR PAL transfer mattresses." On June 12, 1996, Carney Hospital ordered 17 additional "AIR PAL

Transfer Mattresses." *See* JFF ¶ 46.

c. Koury called the air transfer mattresses he order from Davis after he left PTS, "Air Pals" because he wanted to get the order through the Carney Hospital acquisition process quickly. *See* Koury Direct Testimony (Jan. 24, 2001).

***9** d. When Koury placed these orders, he was aware that Davis no longer was working for PTS and that PHSI was a different entity. Brigham was also aware that the Air Pad, TransPad, and HoverMatt were not manufactured and sold by the same entity that manufactured and sold the Air Pal. *See* Koury Direct Testimony (Jan 24, 2001).

8. Burton's Purchases

a. Suzanne Burton of Concord Hospital was not impressed by a product demonstration Weedling conducted after Davis left PTS. *See* Burton Direct Testimony (Jan. 25, 2001).

b. Burton learned that Davis started his own company and, as a result, she decided to cancel her order with Weedling. *See* Burton Direct Testimony (Jan. 25, 2001).

c. Burton was aware that PHSI and PTS were separate companies and that the Air Pal and Air Pad were different products. *See* Burton Direct Testimony (Jan. 25, 2001).

9. At PTS, Weedling received purchase order from individuals who were not currently PTS customers, invoices from part-suppliers for parts that PTS did not order, and a product return of a HoverMatt. *See* Weedling Direct Testimony (Jan. 23, 2001).

10. Davis sent the following seven letters containing literally false statements to prospective customers.

a. A June 29, 1995 letter from Davis to Linda Young of St. Luke's Hospital uses the following phrase: "The AIR PAL, now called the AIR PAD,...."*See* PX-76.

b. A August 14, 1995 letter from Davis to Collins of Medical Center of Delaware uses the following phrase: "... the AIR MOVER transfer system (the new name for the improved AIR PAL)."*See* PX-76.

c. A January 30, 1996 letter from Davis to Patty Smith of Valley View Nursing Center states that "... [PHSI] made special units for the MAYO Clinic to handle 800 lb. patients."*See* PX-77.

d. A February 16, 1996 letter from Davis to Robert Conrad of Inservco states: "I have been in the patient handling arena for twelve years, initially developing a product to facilitate lateral patient transfers. This is the AIR PAD."*See* PX-77.

e. A February 27, 1996 letter from Davis to Deb Fontaine of Workers' Compensation Services states: "Part of the literature describes a product called the AIR PAD. This product has been used in the Shock Trauma unit at the University for several years..... The AIR PAD is a new and improved version of the AIR PAL."*See* PX-77.

f. An April 1, 1996 letter from Davis to Chuck Singleton states: "[Two years ago], the MAYO Clinic asked us to manufacture a transfer pad to move an 800 pound patient off the OR table."*See* PX-77.

g. A November 8, 1996 letter from Davis to Linda Young of St. Luke's Hospital states: "[Annette Friday and Chris Collins of the Medical Center of Delaware] may both identify the Trans Pad by its earlier nameAir Pal."*See* PX-77.

D. Breach of Fiduciary Duty [FN6]

FN6. At mid-trial, I granted defendants' motion for judgment on partial findings with regard to the breach of fiduciary duty claim as to sales made to Frankford Hospital. Therefore, the breach of fiduciary duty claim applies only to sales made to

the Medical Center of Delaware.

***10** 1. In 1990, the Medical Center of Delaware did a pilot evaluation of the A.I.R. PAL. Davis was PTS's contact with the Medical Center for this evaluation. The evaluation provided a cost justification for using the AIR PAL and, as a result, the Center purchased several air transfer mattresses. *See* JFF ¶ 27.

2. In 1994, the Medical Center of Delaware decided to conduct a larger evaluation with vertical lift, patient positioning devices, and patient transfer devices. While Davis was still a PTS employee, Collins told Davis that the Medical Center was planning to conduct this evaluation. *See* JFF ¶ 27; Collins Direct Testimony (Jan. 26, 2001).

3. It is undisputed that, before Davis left PTS in November 1994, Davis told Weedling that the Medical Center of Delaware was "about to pop." Weedling understood this to mean that the Medical Center of Delaware wanted to purchase additional Air Pals. *See* DX-83 (Weedling Deposition), at 243.

4. Weedling never followed up on this information until he made a sales presentation to the Medical Center of Delaware in late 1995 or early 1996. Hospital officials informed Weedling that they were aware of the difference between PTS and PHSI. *See* Cross Examination of Weedling (Jan. 23, 2001); Weedling Rebuttal Testimony (Feb. 1, 2001).

5. Davis did not contact anyone about starting his own company before he left PTS.

6. After Davis left, Weedling sold three air transfer mattresses to the Medical Center of Delaware. However, the mattresses were not purchased by Collins's department at the Medical Center of Delaware. *See* Cross Examination of Weedling during Rebuttal (Feb. 1, 2001).

7. Collins preferred to purchase products from Davis because Davis was willing to adapt air transfer mattresses based on her feedback about their performance. Collins Re-Direct Testimony (Jan. 26, 2001).

8. The Medical Center of Delaware purchased approximately $70,000 worth of air transfer mattresses from Davis between September 1995 and September 1996. *See* Cross Examination of Davis (Feb. 1, 2001).

E. Conversion of Corporate Assets [FN7]

FN7. During closing arguments, plaintiffs dropped all of their conversion of corporate assets claims other than their claim involving the demonstration kit.

1. Davis did not tell Weedling that he had a demonstration scheduled at Frankford Hospital the day his employment was terminated. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

2. Davis kept the demonstration kit that he had in his car when his employment was terminated on November 15, 1994. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

3. Despite Weedling's claim to the contrary, on November 15, 1994, Weedling did not ask Davis if he had any PTS property in his possession. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

4. Davis is no longer in possession of the demonstration kit. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

F. Misappropriation of Trade Secrets [FN8]

FN8. At mid-trial, I granted defendants' motion for judgment on partial findings with regard to: 1) customer lists that were published by PTS, 2) sales records from 1993-94 that were Davis's personal records of his progress. Therefore, the misappropriation of trade secrets claim applies only to the vendor list, the part numbers and prices list found in PX-26, the contact list

found in PX-60, and the drawings that were in Davis's possession in March 1997.

1. In March 1997, the following items were in Davis's possession:

a. A folder labeled "Purchase Orders" that contained, among other documents, copies of purchase orders from PTS to vendors for the parts and services used to make the A.I.R. PAL. The purchase orders show the vendor name, contact information, numbers, and prices for parts and services.

b. A folder labeled "Drawings" that contained, among other documents, copies of LCI Medical and PTS development drawings, production drawings, and cutting and sewing instructions for transfer pads from 1990 through 1994.

***11** c. A folder labeled "Drawings-Production" that contained, among other documents, copies of PTS drawings for production of the 1994 design.

d. A folder that contained, among other documents, a copy of PTS's "Cost Justification Report" and copies of testimonial letters and reports that had been sent to PTS.

e. A folder labeled "Originals" containing, among other documents, copies of various PTS correspondence, instructions, price lists, user lists, packing lists, evaluation forms, warranty forms and definitions, and test reports.

f. A folder labeled "PTS/Weedling Documents" containing copies of various LCI Medical, PTS, and Weedling documents.

g. Records of the sales demonstrations Davis made while he was employed by PTS.

h. PTS's files regarding dealings with a company named ARJO. *See* JFF ¶ 24.

2. Vendor Lists

a. The identity of the vendors was not confidential and neither LCI Medical nor PTS had any exclusivity agreements with their vendors. *See* Cross Examination of Weedling (Jan. 23, 2001); Wegener Direct Testimony (Jan. 25, 2001).

b. The identity of the vendor from whom a given material is purchased is often marked on the material. *See* Cross Examination of Weedling (Jan. 23, 2001); Wegener Direct Testimony (Jan. 25, 2001).

c. Davis could easily remember the name and locations of each of the limited number of vendors involved without the benefit of any documents.

3. Part Numbers and Prices

a. Davis used almost all of the same vendors as PTS did. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

b. Davis claims that, after he left PTS, he did not have to refer to the part numbers and prices listed in PX-26 because he had already memorized the information. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001). I find this statement not to be credible.

4. Unpublished Customer Contact List

a. Davis took a partial list of PTS customers with him when he left. This list included the contact person for each customer. *See* PX-60.

b. Given his experience, Davis would remember the contact information for some customers. However, there is no proof of how much information he would remember. Still, Davis could easily reestablish contact with customers who would direct him to the correct contact person.

5. Drawings

a. Production staff at PTS did not sign confidentiality agreements. *See* Cross Examination of Weedling (Jan. 23, 2001).

b. While he worked at PTS, Davis kept some files in a work area of the plant that was accessible to employees of Gateway Industrial Services, Inc. *See* James Weedling Direct Testimony (Jan. 24, 2001).

c. Approximately a month after Davis left PTS, Davis asked John Davis (no relation) of PTS to get his design and assembly drawings from PTS. John Davis did, in fact, deliver the documents to Davis. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

d. Davis saved some time because he did not have to take apart an Air Pal, but he could easily do so and reverse engineer the product he desired to sell. *See* Davis Direct Testimony as a Hostile Witness (Jan. 23, 2001).

II. Conclusions of Law

A. Jurisdiction

***12** 1. This court has jurisdiction in this matter pursuant to 28 U.S.C. § 1331, 1338(a), 1338(b), and 1367(a).

B. Applicable Law

1. Patent Infringement

a. The analysis of patent infringement requires two steps. First, the court must determine the meaning and scope of the patent claims that the plaintiff asserts are being infringed. Second, the court compares the properly construed claims to the accused infringing device. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd*,517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

b. In a prior opinion, this court construed the meaning and scope of the disputed limitations in claim sixteen of the '873 patent as follows:

(1) The phrase "partition members having laterally extending portions and longitudinally extending portions" in the third subset of limitations in claim sixteen "describes partition members that each have at least one laterally extending portion and at least one longitudinally extending portion."*See Patient Transfer Systems, Inc. v. Patient Handling Solutions, Inc.*, No. CIV.A. 97-1568, 2000 WL 726792, *2-5 (E.D.Pa.2000).

(2) The third subset of limitations in claim sixteen places restrictions on the partition members that form the "side-by-side, laterally extending elongated chambers," but on no other partition members in the invention. *See id.* at *5-6.

(3) The longitudinally extending portions of the "partition members having laterally extending portions and longitudinally extending portions" described in the third subset of limitations in claim sixteen do not need to be perpendicular to the laterally extending portions of those partition members. Instead, "the longitudinally extending portions must extend more in the direction of the longitudinal axis ... than in the direction of the lateral or transverse axis...."*See id.* at *6-7.

c. A patent may be infringed by literal infringement, or, alternatively, under what is known as the "doctrine of equivalents." *See Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 796-97 (Fed.Cir.1990).

d. In order to establish literal infringement of the patent, the patent owner must demonstrate, by a preponderance of evidence, that the accused device contains every limitation in the asserted claims. "If even one limitation is missing or not met as claimed, there is no literal infringement."*Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 980 (Fed.Cir.1999), *cert. denied*,529 U.S. 1066, 120 S.Ct. 1672, 146 L.Ed.2d 482 (2000).*See WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1350 (Fed.Cir.1999).

e. If a claim is not literally infringed upon by the accused device, it may still be infringed under the doctrine of equivalents if the differences between

the claim and the accused device are insubstantial. *See WMS Gaming, Inc.*, 184 F.3d at 1352-53.

***13** f. Davis as a Co-Inventor

(1) "The inventors as named in an issued patent are presumed to be correct."*See Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed.Cir.1997), *cert. denied*,520 U.S. 1277, 117 S.Ct. 2459, 138 L.Ed.2d 216 (quotation omitted). As a result, the burden of showing nonjoinder of an inventor is on the party claiming nonjoinder, and the party claiming nonjoinder must prove its claim of co-inventorship by clear and convincing evidence. *See id.* at 979-80.

(2) A patented invention may be the work of two or more joint inventors. *See*35 U.S.C. § 116.

(3) "Conception is the touchstone of inventorship.... [Conception] is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice..... Because [conception] is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention."*Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed.Cir.1994), *cert. denied*,516 U.S. 1070, 116 S.Ct. 771, 133 L.Ed.2d 724 (1996) (quotation and citations omitted).

(4) "[T]he test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue."*Id.* at 1228.

(5) It is not necessary for each joint inventor to make the same type or amount of contribution to the invention. "Rather, each needs to perform only a part of the task which produces the invention. On the other hand, one does not qualify as a joint inventor by merely assisting the actual inventor after conception of the claimed invention."*See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed.Cir.1998), *cert. denied*,525 U.S. 923, 119 S.Ct. 278, 142 L.Ed.2d 229. "Thus, the critical question for joint conception is who conceived, as that term is used in the patent law, the subject matter of the claims at issue."*Id.*

(6) As a result, "a co-inventor need not make a contribution to every claim of a patent. A contribution to one claim is enough."*Id.* (citations omitted).

(7) However, "[a]n inventor may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."*Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed.Cir.1985), *cert. dismissed*,474 U.S. 976, 106 S.Ct. 340, 88 L.Ed.2d 326 (quotation omitted).

***14** (8) An alleged co-inventor's testimony with respect to the facts underlying his claim of co-inventorship cannot, standing alone, rise to the level of clear and convincing proof. The testimony must be corroborated by independent evidence. *See Price v. Symsek*, 988 F.2d 1187, 1194-96 (Fed.Cir.1993).

(9) Corroborative evidence can take a variety of forms, including contemporaneous documents, circumstantial evidence about the inventive process, and the testimony of witnesses other than that the alleged inventor. *See Ethicon, Inc.*, 135 F.3d at 1461.

(10) All of the relevant evidence put forth by the alleged inventor, including any of his corroborating testimony, must be considered as a whole to determine whether he conceived the invention. "In other words, an inventor can conceivably prove prior conception by clear and convincing evidence although no one piece of evidence in and of itself establishes the prior conception."*Price*, 988 F.2d at

1196.

(11) 35 U.S.C. § 256"provides that if 'through [inadvertent] error an inventor is not named in an issued patent ... the Commissioner [of Patents] may ... issue a certificate correcting such error,' and that '[t]he court ... may order correction of the patent ... and the Commissioner shall issue a certificate accordingly.'"*Hess,* 106 F.3d at 979 (alteration in the original).*See Ethicon, Inc.,* 135 F.3d at 1461 ("35 U.S.C. § 256 provides that a co-inventor omitted from an issued patent may be added to the patent by a court 'before which such matter is called in question.' ").

2. False Advertising

a. Section 43(a) of the Lanham Act creates a federal cause of action for a wide variety of acts of unfair competition, including false or misleading advertising. *See Rose Art Indus., Inc. v. Swanson,* 235 F.3d 165, 170 (3d Cir.2000).

b. To prevail on a Lanham Act false advertising claim, a plaintiff must prove that the advertisement is either literally false, or, if it is not literally false, that it is still likely to mislead or deceive consumers. *See Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc.,* 19 F.3d 125, 129-30 (3d Cir.1994).

c. If a court finds that a statement made in advertising is literally false, it may grant relief without considering whether consumers were actually misled. *See id.* at 129.

e. To prove a claim for false advertising under 15 U.S.C. § 1125(a), plaintiff must prove by a preponderance of evidence:

(1) that the defendant has made false or misleading statements as to his own product or another's product;

***15** (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience;

(3) that the deception is material in that it is likely to influence purchasing decision;

(4) that the advertised goods traveled in interstate commerce; and

(5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

See U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia, 898 F.2d 914, 922-23 (3d Cir.1990), *cert. denied,*498 U.S. 816, 111 S.Ct. 58, 112 L.Ed.2d 33 (quoting *Max Daetwyler Corp. v. Input Graphics, Inc.,* 545 F.Supp. 165, 171 (E.D.Pa.1982) (citation omitted).

3. Breach of Fiduciary Duty

a. In Pennsylvania, an officer of a corporation "shall perform his duties as an officer in good faith, in a manner he reasonably believes to be in the best interests of the corporation and with such care, including reasonable inquiry, skill and diligence, as a person of ordinary prudence would use under similar circumstances."15 Pa.C.S.A. § 512(c); *see Confer v. Custom Eng'g Co.,* 952 F.2d 34, 38 (3d Cir.1991).

b. Because directors and officers of a corporation occupy a fiduciary relation toward the corporation for which they work, "they cannot directly or indirectly make any profit at the expense of the corporation."*See Weissman v. Weissman, Inc.,* 382 Pa. 189, 114 A.2d 797, 799 (Pa.1955).

c. In other words, in order to prove a claim of breach of fiduciary duty, the plaintiff must prove by a preponderance of the evidence:

(1) "that the defendant negligently or intentionally failed to act in good faith and solely for the benefit of plaintiff in all matters for which he or she was employed;"

(2) that the plaintiff suffered injury; and

(3) "that the agent's failure to act solely for the plaintiff's benefit ... was a real factor in bring [sic] about plaintiff's injuries."

See McDermott v. Party City Corp., 11 F.Supp.2d 612, 626 n. 18 (E.D.Pa.1998) (quotation omitted).

d. Fiduciary duty may be breached by failing to disclose a material fact. *See In re Allegheny Int'l, Inc.*, 954 F.2d 167, 180 (3d Cir.1992).

e. "[U]nder the law of Pennsylvania[,] employees at will do not breach a fiduciary duty to the employer by making preparations to compete upon termination of employment provided the employee does not use the confidential information of his employer, solicit the customers of his employer, or otherwise engage in conduct directly damaging his employer during the period of employment."*Oestreich v. Environmental Inks and Coatings Corp.*, Civ.A. No. 89-8907, 1990 WL 210599, at *6 (E.D.Pa.1990)(citing *Spring Steels, Inc. v. Molloy*, 400 Pa. 354, 162 A.2d 370 (1960)).

b. Because breach of fiduciary duty is tortious conduct, *see*Restatement (Second) of Torts, § 874 (1979), under Pennsylvania law, it is subject to a two-year statute of limitations period. *See*42 Pa.C.S.A. § 5524(7).

4. Conversion of Corporate Assets

***16** a. In order to prove a claim of conversion of corporate assets, the plaintiff must prove by a preponderance of the evidence:

(1) "the deprivation of another's right of property in, or use or possession of, a chattel;"

(2) "without owner's consent;" and

(3) "without lawful justification."

Bernhardt v. Needleman, 705 A.2d 875, 878 (Pa.Super.1997).

b. "Where one lawfully comes into possession of the chattel, a conversion occurs if a demand for the chattel is made by the rightful owner and the other party refuses to deliver."*The Prudential Insurance Co. v. Stella*, 994 F.Supp. 318, 323 (E.D.Pa.1998) (citing *Norriton East Realty Corp. v. Central-Penn Nat. Bank*, 435 Pa. 57, 254 A.2d 637, 638 (Pa.1969)).

c. Under Pennsylvania law, there is a two year statute of limitations for conversion. *See*42 Pa.C.S.A. § 5524; *Shonberg v. Oswell*, 365 Pa.Super. 481, 530 A.2d 112, 114 (Pa.Super.1987).

d. "It is well settled that the commencement of an action in state court has no effect on the running of the statute with respect to an action filed later in federal court."*Price v. United States*, 466 F.Supp. 315, 318 (E.D.Pa.1979) (citing *Falsetti v. Local Union No.2026, United Mine Workers*, 355 F.2d 658, 662 (3d Cir.1966)).

e. "It is well-established that Pennsylvania law recognizes an exception to the statute of limitations which delays the running of the statute until the plaintiff knew, or through the exercise of reasonable diligence should have known, of the injury and its cause. Courts employ the same 'knew or should have known' standard whether the statute is tolled because of the discovery rule or because of fraudulent concealment."*Beauty Time, Inc. v. VU Skin Sys., Inc.*, 118 F.3d 140, 144 (3d Cir.1997) (quotations omitted).

f. "Reasonable diligence has been defined as follows: 'A fair, proper and due degree of care and acting, measured with reference to the particular circumstances; such diligence, care, or attention as might be expected from a man of ordinary prudence and activity.'"*Id.* (quoting *Black's Law Dictionary* 457 (6th ed. 1991)).

g. "[T]here are few facts which diligence cannot discover, but there must be some reason to awaken inquiry and suggest investigation."*Id.* (citation omitted).

h. Because the statute of limitations is an affirmative defense, the initial burden of establishing its applicability to a particular claim rests with the defendant. *See Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 487 (3d Cir.1985). However, under Pennsylvania law, the burden shifts to the plaintiff if he or she asserts that the statute of limitations should be tolled by the discovery rule. *See id.*If the plaintiff satisfies this burden, the discovery rule delays the accrual of a cause of action until the plaintiff was aware or should have been aware that an injury occurred. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1386 (3d Cir.1994).

5. Misappropriation of Trade Secrets

***17** a. To establish a claim of misappropriation of trade secrets, the plaintiff must prove the following:

(1) the existence of trade secrets.

(2) that the secrets were valuable to the plaintiff and important in the conduct of plaintiff's business.

(3) that the plaintiff had the right to the use and enjoyment of the secrets; and

(4) that the secrets were communicated to the defendant while he was employed in a position of trust and confidence under such circumstances as to make it inequitable and unjust for him to disclose the secrets to others, or to make use of them himself.

See SI Handling Sys., Inc. v. Heisley, 753 F.2d 1244, 1255 (3d Cir.1985).

b. Pennsylvania courts have adopted the definition of a trade secret given in the Restatement of Torts, § 757, comment b (1939):

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

Id.

c. "Matters which are fully disclosed by a marketed product and are susceptible to 'reverse engineering'-i.e., starting with the known product and working backward to divine the process which aided in its manufacture, cannot be protected as trade secrets."*Id.* (quotation omitted).

d. In determining whether information constitutes a trade secret, a court should consider the extent to which the information is known outside the plaintiff's business; the extent to which it is known by employees and others; the measures taken to guard the secrecy of the information; the value of the information; the money and effort expended by the owner to develop the information; and the ease with which the information could be properly acquired or duplicated by others. *See id.* at 1256 (citing Restatement of Torts § 757 comment b (1939)).

e. Confidential customer lists can be protected as trade secrets under Pennsylvania law. *See id.* at 1258.However, "[c]ustomer lists ... cannot be trade secrets if they are easily or readily obtained, without great difficulty, through some independent source other than the trade secret holder. Accordingly, courts have denied protection to customer lists which are easily generated from trade journals, ordinary telephone listings, or an employee's general knowledge of who, in an established industry, is a potential customer for a given product."*BIEC Int'l, Inc. v. Global Steel Servs., Ltd.*, 791 F.Supp. 489, 545 (E.D.Pa.1992) (citations omitted).

f. "The secrecy in which a purported trade secret is kept need not be absolute but reasonable precautions under the circumstances must be taken to prevent disclosures to unauthorized third partes. The degree of secrecy must be such that it would be dif-

ficult for others to obtain the information without using improper means."*National Risk Mgmt., Inc. v. Bramwell,* 819 F.Supp. 417, 431 (E.D.Pa.1993).

g. Under Pennsylvania law, a claim of misappropriation of trade secrets is subject to a two year statute of limitations. *See*42 Pa.C.S.A. § 5524; *Advanced Power Sys., Inc. v. Hi-Tech Sys., Inc.,* 801 F.Supp. 1450, 1455 (E.D.Pa.1992).

C. Liability

1. PTS's Patent Infringement Claim

***18** a. PTS claims that the defendants' TransPad and HoverMatt air transfer mattresses violate the '873 patent, which is held by PTS.

b. PTS has failed to demonstrate, by a preponderance of the evidence, that the TransPad and the HoverMatt contain every limitation in the claims asserted by the '873 patent. In particular, PTS has failed to establish that any portion of the partition members in these air transfer mattresses is both: 1) attached to the top and bottom sheets of the air transfer mattress, and 2) extends more in the direction of the longitudinal axis than in the direction of the lateral or transverse axis. PTS concedes that if this is true, which I have found it is, there is no literal infringement.

c. PTS has also failed to demonstrate, by a preponderance of the evidence, that the differences between claim sixteen and the TransPad or HoverMatt are insubstantial.

d. Therefore, PTS's patent infringement claim fails under both a literal infringement and a "doctrine of equivalents" theory of infringement.

e. Furthermore, PTS's patent infringement claim fails because the defendants have proven, by clear and convincing evidence, that Davis is a joint inventor of the subject matter of the '873 patent. In particular, the drawings in PX-11 and the testimony of Swallen, Wegener, and Attorney Zinn corroborate Davis's claim that he conceived at least one claim of the '873 patent. Moreover, Weedling knew of the standard of inventorship and he added Davis a co-inventor on the '189 and '873 patent applications.

2. PTS's False Advertising Claim

a. PTS claims that the defendants violated the Lanham Act by utilizing false advertising to promote their air transfer mattress.

b. PTS has proven, by a preponderance of evidence, that the defendants have engaged in false advertising in violation of the Lanham Act by sending to prospective customers seven letters, noted above in Section I.C. 10, that contain statements that are literally false as a factual matter.

c. Moreover, PTS has also proven, by a preponderance of evidence, that the defendants' use of testimonial letters and evaluation reports, noted above in Section I.C. 1, constitutes false advertising in violation of the Lanham Act. Although the statements in these testimonial letters and evaluation reports are literally true, PTS has demonstrated that such statements have misled or confused consumers. The fact that PTS received purchase orders from individuals who were not currently PTS customers, invoices from part-suppliers for parts that PTS did not order, and a product return of a HoverMatt, demonstrate actual confusion on part of consumers and the likelihood of injury to PTS in terms of declining sales, loss of good will, etc.

3. PTS's Breach of Fiduciary Duty Claim

***19** a. PTS claims that Davis breached the fiduciary duty he owed to PTS by not disclosing that the Medical Center of Delaware was conducting an evaluation of air transfer mattresses. However, PTS concedes that Davis disclosed that the Medical Center of Delaware was "about to pop" which is functionally equivalent and put PTS on notice that it should have pursued the corporate opportunity

immediately after Davis left.

b. PTS has failed to prove, by a preponderance of evidence, two of the three elements of a breach of fiduciary duty.

c. First, because Davis, before he left PTS, told Wheeling that the Medical Center of Delaware was "about to pop," PTS has failed to prove that Davis failed to act in good faith and solely for the benefit of PTS while he was employed by PTS.

d. Second, because Wheeling was in contact with the Medical Center of Delaware after Davis left PTS, PTS sold three mattresses to the Medical Center of Delaware during the relevant time period, and Collins expressed a preference for dealing with Davis after she became aware of the difference between the two corporations, PTS has not established that any conduct by Davis was a real factor in bringing about any injury claimed by PTS.

4. PTS's Conversion of Corporate Assets Claim

a. PTS claims that Davis unlawfully converted a corporate asset when he kept PTS's demonstration kit after he ceased to work there.

b. PTS's conversion of corporate assets claim fails because it is barred by the statute of limitations.

c. PTS knew or, through the exercise of reasonable diligence, should have known that Davis had the demonstration kit on November 14, 1994. Although PTS filed a state lawsuit on November 1, 1995, because this lawsuit was not filed until February 27, 1997, PTS's conversion of corporate assets claim is barred by the statute of limitations. *See Price v. U.S.*, 466 F.Supp. 315, 318 (E.D.Pa.1979) ("It is well settled that the commencement of an action in state court has no effect on the running of the statute with respect to an action filed later in federal court.") (citing *Falsetti v. Local Union No.2026, United Mine Workers*, 355 F.2d 658, 662 (3d Cir.1966)).

d. PTS has not established a factual basis to toll the statute of limitations by the discovery rule.

5. PTS's Misappropriation of Trade Secrets Claim

a. PTS claims that Davis misappropriated PTS's trade secrets in the form of a vendor list, a part numbers and prices list, the unpublished contact list found in PX-60, and drawings.

b. With regard to the vendor list, PTS's misappropriation of trade secrets claim fails because the vendor list does not constitute a trade secret. First, PTS took few if any measures to guard the secrecy of the information contained in the vendor list. For example, the identity of the vendors was not confidential and neither LCI Medical nor PTS had any exclusivity agreements with their vendors. Second, Davis would have been easily capable of replicating the vendor list from memory because: the identity of the vendor from whom PTS purchased a given material was often marked on the material; there are only a limited number of vendors that provide products used in the construction of the Air Pal; and Davis had extensive knowledge about the construction of the Air Pal.

c. With regard to the part numbers and prices list, PTS has proven that the defendants have misappropriated PTS's trade secret. First, the part numbers and prices list constitutes a trade secret because the level of detail contained in the information compiled in this list would have been very difficult for Davis to replicate from memory. Furthermore, the defendants have not contested PTS's claims that: the list is valuable because it simplifies the ordering process and constitutes the basis for production cost approximations; PTS had the right to its use and enjoyment; and Davis became aware of this list while he was an officer of PTS.

***20** d. With regard to the contact list, PTS's misappropriation of trade secrets claim fails because the contact list does not constitute a trade secret. The contact list does not constitute a trade secret be-

cause, given his years of experience selling the Air Pal, Davis could have easily remembered the contact information for some customers. For those customers whose contact person he could not remember, Davis would have been easily able to reestablish contact with the customer who could then direct him to the correct contact person.

e. With regard to the drawings, PTS's misappropriation of trade secrets claim fails because the drawings do not constitute trade secrets. First, the drawings are not trade secrets because "matters which are fully disclosed by a marketed product and are susceptible to 'reverse engineering'-i.e., starting with the known product and working backward to divine the process which aided in its manufacture, cannot be protected as trade secrets."*See SI Handling Systems, Inc.*, 753 F.2d at 1255. Second, there is considerable evidence that PTS did not take appreciable measures to guard the secrecy of the information contained in the drawings. Third, given that Davis drafted most of the drawings, he would have been capable of replicating them.

D. Remedy

1. Because Davis is a joint inventor of the subject matter of the '873 patent, I will order the correction of the '873 patent.

2. Because the defendants have engaged in false advertising in violation of the Lanham Act by sending: 1) seven letters containing literally false statements to prospective customers, *see* Section I.C. 10, and 2) misleading testimonial letters and evaluation reports to prospective customers, *see* Section I.C. 1; and have misappropriated PTS's trade secret, as embodied in the part numbers and prices list, *see* PX-26, I will order a trial on damages arising out of these claims.

Order

AND NOW, this day of August, 2001, having considered both parties' pre- and post-trial filings as well as all of the testimony and exhibits offered at trial on the issue of liability, in accordance with the aforesaid findings of fact and conclusions of law, IT IS HEREBY ORDERED THAT judgment is entered as follows:

1. Because David T. Davis is a joint inventor of the subject matter of the '873 patent, the court orders the correction of the '873 patent by the Commissioner of Patents pursuant to 35 U.S.C. § 256 so that David T. Davis is reinstated as a joint inventor of the '873 patent;

2. Defendants have engaged in false advertising in violation of the Lanham Act by sending: 1) seven letters containing literally false statements to prospective customers, and 2) misleading testimonial letters and evaluation reports to prospective customers; and have misappropriated PTS's trade secret, as embodied in the part numbers and prices list; and

***21** 3. The parties shall notify the court within ten days as to: a) how soon they will be ready for a trial on damages based on the judgments against the defendants on the false advertising and misappropriation of trade secret claims; and b) their estimate as to how long a trial on damages will last.

E.D.Pa.,2001.
Patient Transfer Systems, Inc. v. Patient Handling Solutions, Inc.
Not Reported in F.Supp.2d, 2001 WL 936641 (E.D.Pa.)

END OF DOCUMENT

APPENDIX 6

C

MasterCard Intern. Inc. v. Nader 2000 Primary Committee, Inc.
S.D.N.Y.,2004.

United States District Court,S.D. New York.
MASTERCARD INTERNATIONAL INCORPORATED Plaintiffs,
v.
NADER 2000 PRIMARY COMMITTEE, INC., Nader 2000 General Committee, Inc., and Ralph Nader, Defendants.
No. 00 Civ.6068(GBD).

March 8, 2004.

Background: Financial services company that had commissioned authorship of advertisements using phrase "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," sued presidential candidate and his political committee for use of slogans similar to its service marks, alleging claims for unfair competition, misappropriation, trademark infringement, trademark dilution under the Federal Trademark Act and state and common law, as well as copyright infringement under the Copyright Act. Defendants moved for summary judgment.

Holdings: The District Court, Daniels, J., held that:
(1) plaintiff failed to establish likelihood of confusion, as required to support trademark infringement claims;
(2) state claims for unfair competition and misappropriation were preempted by the Copyright Act;
(3) lack of likelihood of consumer confusion defeated palming off claim under New York law;
(4) there was no evidence of trademark dilution;
(5) defendants' use of plaintiff's copyrighted works was fair use, and thus, not an infringement; and
(6) defendants' use of plaintiff's copyrighted works was not a material deceptive act or practice directed to consumers that caused actual harm, as would support deceptive acts or practices claim.

Motion granted.

West Headnotes

[1] Trademarks 382T 1092

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion
382Tk1090 Nature of Marks
382Tk1092 k. Strength or Fame of Marks; Degree of Distinctiveness. Most Cited Cases
(Formerly 382k350.1)
For purposes of determining likelihood of confusion to public in trademark infringement action based on presidential candidate and his political committee's use of slogans similar to financial services company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," marks were strong enough to have become a part of present-day American popular culture, and thus had acquired secondary meaning. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[2] Trademarks 382T 1097

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion
382Tk1093 Relationship Between Marks
382Tk1097 k. Examination and Comparison; Construction as Entirety. Most Cited Cases
(Formerly 382k350.1)

Trademarks 382T 1098

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion
382Tk1093 Relationship Between Marks
382Tk1098 k. Appearance, Sound, and

Meaning. Most Cited Cases
(Formerly 382k350.1)
Presidential candidate and his political committee's use of word "priceless" and phrase "there are some things money can't buy" in same look, sound, and commercial impression as employed by financial services company established sufficient degree of similarity to company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," as to support finding of likelihood of confusion to public, for purposes of company's trademark infringement action against candidate and committee. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[3] Trademarks 382T 1104

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion
382Tk1100 Relationship Between Goods or Services Underlying Marks
382Tk1104 k. Markets and Territories; Competition. Most Cited Cases
(Formerly 382k350.1)
For purposes of determining likelihood of confusion to public in trademark infringement action based on presidential candidate and his political committee's use of slogans similar to financial services company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," plaintiff failed to show proximity between services and political candidacy, or likelihood that defendants would "bridge the gap" into its product or service line, or that it would have any direct involvement in supporting a candidate in a political presidential campaign. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[4] Trademarks 382T 1086

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion
382Tk1083 Nature of Confusion
382Tk1086 k. Actual Confusion. Most Cited Cases
(Formerly 382k350.1)
Presidential candidate and his political committee's use of word "priceless" and phrase "there are some things money can't buy" in same look, sound, and commercial impression as employed by financial services company did not create actual confusion with respect to company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," as would support finding of likelihood of confusion to public, for purposes of company's trademark infringement action against candidate and committee. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[5] Trademarks 382T 1111

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion
382Tk1111 k. Intent; Knowledge of Confusion or Similarity. Most Cited Cases
(Formerly 382k350.1)
Presidential candidate and his political committee's use of word "priceless" and phrase "there are some things money can't buy" in same look, sound, and commercial impression as financial services company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," was not intended to confuse public, as would support finding of likelihood of confusion to public, for purposes of company's trademark infringement action against candidate and committee. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[6] Trademarks 382T 1105

382T Trademarks
382TIII Similarity Between Marks; Likelihood of Confusion

382Tk1100 Relationship Between Goods or Services Underlying Marks

382Tk1105 k. Relative Quality. Most Cited Cases

(Formerly 382k350.1)

For purposes of determining likelihood of confusion to public in trademark infringement action based on presidential candidate and his political committee's use of slogans similar to financial services company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," there was no reasonable comparison to be made between quality of plaintiff's products and services and value of defendants' politics. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[7] Trademarks 382T 1112

382T Trademarks

382TIII Similarity Between Marks; Likelihood of Confusion

382Tk1112 k. Persons Confused; Circumstances of Sale. Most Cited Cases

(Formerly 382k350.1)

For purposes of determining likelihood of confusion to public in trademark infringement action based on presidential candidate and his political committee's use of slogans similar to financial services company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," plaintiff's customers were generally sophisticated enough to decipher between plaintiff's commercial purposes and defendants' political agenda. Lanham Trade-Mark Act, §§ 32(1), 43(a), 15 U.S.C.A. §§ 1114(1), 1125(a).

[8] States 360 18.84

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.83 Trade Regulation; Monopolies

360k18.84 k. In General. Most Cited Cases

Antitrust and Trade Regulation 29T 14

29T Antitrust and Trade Regulation

29TII Unfair Competition

29TII(A) In General

29Tk14 k. Preemption. Most Cited Cases

(Formerly 382k423.1 Trade Regulation)

Financial services company's state law claims for unfair competition and misappropriation against presidential candidate and his political committee, based on their alleged use of advertisement derived from company's copyrighted advertising, were preempted by the Copyright Act; advertisements fell within subject matter of the Act, and unfair competition and misappropriation claims were grounded solely in defendants' copying of copyrighted expression. 17 U.S.C.A. § 301(a), (b)(1).

[9] Trademarks 382T 1428(1)

382T Trademarks

382TVIII Violations of Rights

382TVIII(A) In General

382Tk1423 Particular Cases, Practices, or Conduct

382Tk1428 Passing Off or Palming Off

382Tk1428(1) k. In General. Most Cited Cases

(Formerly 382k404)

Under New York law, presidential candidate and his political committee's use of slogans similar to financial services company's service marks "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," did not create likelihood of consumer confusion, as would support palming off claim.

[10] Trademarks 382T 1469

382T Trademarks

382TVIII Violations of Rights

382TVIII(B) Dilution

382Tk1469 k. Nature of Defendant's Use; Use in Commerce. Most Cited Cases
(Formerly 382k366)

Trademarks 382T 1524(1)

382T Trademarks
382TVIII Violations of Rights
382TVIII(D) Defenses, Excuses, and Justifications
382Tk1521 Justified or Permissible Uses
382Tk1524 Expressive Use; Commentary
382Tk1524(1) k. In General. Most Cited Cases
(Formerly 382k366)
Presidential candidate and his political committee's use of financial services company's trademarks, "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," was not commercial, but rather political in nature, and therefore was exempted from coverage by the Federal Trademark Dilution Act. 15 U.S.C.A. § 1125(c)(4)(B).

[11] Trademarks 382T 1464

382T Trademarks
382TVIII Violations of Rights
382TVIII(B) Dilution
382Tk1462 Reduction of Mark's Capacity to Identify; Blurring
382Tk1464 k. Particular Cases. Most Cited Cases
(Formerly 382k366)
Even if presidential candidate and his political committee's use of financial services company's trademarks, "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," was commercial, rather than political in nature, such use did not dilute distinctiveness of company's marks in violation of the Federal Trademark Dilution Act; plaintiff failed to show that defendants' use of its marks lessened their value or capacity to identify and distinguish its goods or services. 15 U.S.C.A. § 1125(c).

[12] Trademarks 382T 1464

382T Trademarks
382TVIII Violations of Rights
382TVIII(B) Dilution
382Tk1462 Reduction of Mark's Capacity to Identify; Blurring
382Tk1464 k. Particular Cases. Most Cited Cases
(Formerly 382k366)
Presidential candidate and his political committee's use of financial services company's trademarks, "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," did not create even a likelihood of dilution of company's marks in violation of the New York anti-dilution law; plaintiff failed to show that defendants' limited and political use of its marks could weaken their ability to serve as a unique identifier of its goods or services. McKinney's General Business Law § 360-1.

[13] Copyrights and Intellectual Property 99 67.3

99 Copyrights and Intellectual Property
99I Copyrights
99I(J) Infringement
99I(J)1 What Constitutes Infringement
99k67.3 k. Other Works. Most Cited Cases
Presidential candidate and his political committee's use of financial services company's copyrighted service marks, "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," was fair use, and thus, not an infringement in violation of the Copyright Act, where allegedly infringing political advertisement was a parody, substance of defendants' message was different from message of plaintiff's advertisements, and use of allegedly infringing advertisement did not harm potential market for or value of copyrighted work. 17 U.S.C.A. § 107(2).

[14] Trademarks 382T 1427

382T Trademarks
382TVIII Violations of Rights
382TVIII(A) In General
382Tk1423 Particular Cases, Practices, or Conduct
382Tk1427 k. Advertising or Marketing. Most Cited Cases
(Formerly 92Hk7 Consumer Protection)
Under New York law, presidential candidate and his political committee's use of financial services company's trademarks, "THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS," was not a material deceptive act or practice directed to consumers that caused actual harm, as would support deceptive acts or practices claim, where political advertisement was not used in connection with sale or promotion of a product or service, nor in the conduct of business, trade, or commerce. McKinney's General Business Law § 349.

Trademarks 382T 1800

382T Trademarks
382TXI Trademarks and Trade Names Adjudicated
382Tk1800 k. Alphabetical Listing. Most Cited Cases
(Formerly 382k736)
PRICELESS.

Trademarks 382T 1800

382T Trademarks
382TXI Trademarks and Trade Names Adjudicated
382Tk1800 k. Alphabetical Listing. Most Cited Cases
(Formerly 382k736)
THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD.

MEMORANDUM OPINION AND ORDER

DANIELS, J.
***1** Plaintiff MasterCard filed an action against defendants Ralph Nader and his political committee, alleging unfair competition, misappropriation, trademark infringement and dilution of MasterCard's trademarks under the Federal Trademark Act and state and common law. Plaintiff also alleged infringement of plaintiff's copyright under the Copyright Act of 1976. Defendants filed a motion for summary judgment. Defendants' motion for summary judgment is hereby GRANTED in its entirety.

BACKGROUND

MasterCard, a Delaware corporation with its principle place of business in New York, is a large financial institution that engages in the interchange of funds by credit and debit payment cards through over 23,000 banks and other foreign and domestic member financial institutions. Since Fall of 1997, MasterCard has commissioned the authorship of a series of advertisements that have come to be known as the "Priceless Advertisements." These advertisements feature the names and images of several goods and services purchased by individuals which, with voice overs and visual displays, convey to the viewer the price of each of these items. At the end of each of the Priceless Advertisements a phrase identifying some priceless intangible that cannot be purchased (such as "a day where all you have to do is breathe") is followed by the words or voice over: "Priceless. There are some things money can't buy, for everything else there's MasterCard."

In August 2000, MasterCard became aware that Ralph Nader and his presidential committee were broadcasting an allegedly similar advertisement on television that promoted the presidential candidacy of Ralph Nader in the 2000 presidential election. That political ad included a sequential display of a series of items showing the price of each ("grilled tenderloin for fund-raiser; $1,000 a

plate;""campaign ads filled with half-truths: $10 million;""promises to special interest groups: over $100 billion"). The advertisement ends with a phrase identifying a priceless intangible that cannot be purchased ("finding out the truth: priceless. There are some things that money can't buy"). The resulting ad (the "Nader ad") was shown on television during a two week period from August 6-17, during the 2000 presidential campaign, and also appeared on the defendants' web site throughout that campaign. Plaintiff sent defendants a letter explaining its concern over the similarity of the commercials, and suggested that defendants broadcast a more "original" advertisement. When plaintiff contacted representatives of defendants a few days later, plaintiff MasterCard advised defendants to cease broadcasting their political advertisement due to its similarity with MasterCard's own commercial advertisement and resulting infringement liability.

When the parties could not come to an agreement, on August 16, 2000, MasterCard filed a complaint alleging the following counts against Ralph Nader and his presidential committee; trademark infringement and false designation of origin in violation of Section 43(a) of the Lanham Act; infringement of a registered trademark in violation of Section 32(1) of the Lanham Act; dilution in violation of Section 43(c) of the Lanham Act; copyright infringement in violation of the Copyright Act; unfair competition; misappropriation; infringement of New York Common Law Trademark Rights; dilution under New York law; and deceptive trade practices. Plaintiff sought a preliminary injunction during the 2000 presidential campaign which was denied by this Court. Thereafter, defendants moved for summary judgment on all nine of plaintiff's counts.

DISCUSSION

***2** Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law."Fed.R.Civ.P. 56(c); *Nebraska v. Wyoming*, 507 U.S. 584, 590, 113 S.Ct. 1689, 1694, 123 L.Ed.2d 317 (1993). The burden of demonstrating that no factual dispute exists is on the moving party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once the moving party has met this burden, the nonmoving party "must set forth specific facts showing that there is a genuine issue for trial ."Fed.R.Civ.P. 56(e). In deciding a motion for summary judgment, a court must resolve all ambiguities and draw all reasonable inferences in favor of the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91L.3d.2d202 (1986). Summary judgment should be granted only when no reasonable trier of fact could find in favor of the nonmoving party. *Gallo v. Prudential Residential Services, Ltd.*, 22 F.3d 1219, 1224 (2d Cir.1994).

1. *Trademark Infringement*

MasterCard's first count is based on Section 43(a) of the Trademark Act, 15 U.S.C. Section 1125(a). Plaintiff claims that defendants have used two of MasterCard's service marks-"THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS" to misrepresent that the 2000 presidential candidacy of Ralph Nader for the office of President of the United States was endorsed by MasterCard. (Complaint ¶ 23). Plaintiff's second count also pleads a claim for trademark infringement due to defendants' use of the two federally registered trademarks, ("THERE ARE SOME THINGS MONEY CAN'T BUY. FOR EVERYTHING ELSE THERE'S MASTERCARD," and "PRICELESS"), pursuant to Section 32(1) of the Trademark Act, 15 U.S.C. Section 1114(1).

In trademark infringement cases, the Court must apply the undisputed facts to the balancing test outlined in *Polaroid Corp. v. Polarad Elecs., Corp.*, 287 F.2d 492, 495 (2d Cir.1961), and may grant summary judgment where it finds, as a matter of

law, that there is no likelihood of confusion to the public. *See*Lois Sportswear, USA, Inc. v. Levi Strauss & Co., 799 F.2d 867 (2d Cir.1986); *Lang v. Retirement Living Publ'g Co.*, 949 F.2d 576, 580 (2d Cir.1991). In determining whether there is a likelihood of confusion between MasterCard's Priceless Advertisements and Ralph Nader's Political Ad, the Court weighs eight factors, as articulated in *Polaroid*, 287 F.2d at 495:(1) strength of the Plaintiff's mark; (2) degree of similarity between the two marks; (3) proximity of the products or services; (4) likelihood that the prior owner will "bridge the gap" into the newcomer's product or service line; (5) evidence of actual confusion between the marks; (6) whether the defendant adopted the mark in good faith; (7) the quality of defendants' products or services; and (8) sophistication of the parties' consumers. *See*Time, Inc. v. Petersen Publishing Co., 173 F.3d 113, 117 (2d Cir.1999); *See also*Morningside Capital Group, 182 F.3d 133, 137 (2d Cir.1999).

***3** [1] In demonstrating the strength of the trademark, the plaintiff must establish either that the mark is inherently distinctive or alternatively, that the mark has acquired secondary meaning. *See*McGregor-Doniger Inc. v. Drizzle, Inc., 599 F.2d 1126, 1131 (2d Cir.1979). MasterCard's marks, "priceless" and "there are some things money can't buy, for everything else there's MasterCard," are registered. MasterCard asserts that their marks have attained secondary meaning. Defendants concede that MasterCard's Priceless Advertisements are strong enough to have become a part of present-day American popular culture. (Def.'s Mem. in Supp. of Mot. for Summ. J., p. 19). The strength of MasterCard's trademarks is indisputable.

[2] In determining the second factor, the similarity of the marks in issue, a court must consider whether the marks create the same overall commercial impression when viewed separately. *See*Nikkon, Inc. v. Ikon Corp., 803 F.Supp. 901, 926 (S.D.N.Y.1992). A court may rely upon its own visual inspection in making this determination. *e.g.*,Venetianaire Corp. v. A & P Import Co., 429 F.2d 1079, 1081 (2d Cir.1970). In this instance, it is not necessary for the Court to do so, because once again, defendants do not dispute that the Nader Ad employs the word "priceless" in the same manner used by MasterCard in its television advertisements. (Zopoth Aff. ¶¶ 304, Exs. 9 and 10). The Nader Ad also employs the phrase "there are some things money can't buy," which is part of a MasterCard trademark. Defendants do not dispute that they employ that phrase in the same look, sound and commercial impression as employed by MasterCard. *Id.*

[3] The third and fourth factors, the proximity of the products or services and the likelihood that the prior user will bridge the gap, respectively, weigh in favor of defendants. There is little similarity between MasterCard's credit and debit card business and Ralph Nader's political candidacy. There is little likelihood and no evidence that MasterCard, a financial services company, would have any direct involvement in supporting a candidate in a political presidential campaign. Similarly, neither Ralph Nader nor his political campaign committee have expressed any desire or intent to enter the credit card business or offer the public any direct financial services. (Def's Mem. in Supp. of Summ. J., p. 20).

[4] Evidence of actual confusion, the fifth factor, also weighs in favor of defendants. This factor is perhaps the most significant when considering the overall likelihood of confusion by the public. "The best evidence of likelihood of confusion is the occurrence of actual confusion and mistakes."*Lambda Electronics Corporation, et al. v. Lambda Technology, Inc.*, 515 F.Supp. 915, 926 (S.D.N.Y.1981). While it is not essential for a finding of trademark infringement to demonstrate actual confusion, "there can be no more positive proof of likelihood of confusion than evidence of actual confusion."*Id.*, at 926-27 (citing *Grotrian, et al. v. Steinway & Sons*, 365 F.Supp. 707, 715-16 (S.D.N.Y.1973), *aff'd*,523 F.2d 1331 (2d Cir.1975)). In *Lang v. Re-*

tirement Living Publishing Co., 949 F.2d 576 (2d Cir.1991), the Second Circuit affirmed the trial court's grant of summary judgment to the defendants on the ground that plaintiff had failed to raise a genuine issue of fact on likelihood of confusion. In that case, where the plaintiff, whose trade name was similar to that of defendants, received 400 phone calls and several letters from third parties attempting to reach the defendant, the Court explained that the Lanham Act seeks to prevent consumer confusion that enables a seller to pass off his goods as the goods of another, not to protect against confusion generally. *Id.,* at 583.As evident by the present record, out of 452 e-mails to MasterCard regarding the Nader Ad, only two are relied upon as possibly reflecting confusion. (Grossman Aff. ¶ 9, Exs. 4). This is certainly not enough to show actual confusion or that such confusion inflicted commercial injury to MasterCard. In support of its argument that actual confusion exists, MasterCard also relies on the written transcript of a broadcast of CNN's *Late Edition,* during which Connecticut Senator Christopher Dodd stated that he thought the Nader Advertisement was a credit card ad. A viewing of a tape of that program shows Senator Dodd laughing at his own joke, while speaking the words on which MasterCard relies to establish actual confusion. It is little or no evidence of actual confusion. Even if Senator Dodd had actually been confused, a few isolated instances of actual confusion are not sufficient to defeat a motion for summary judgment. *SeeBrockmeyer v. The Hearst Corporation, et al.,* 428, F.Supp.2d 281, 298 (S.D.N.Y.2003) (“one anecdotal instance of purported actual confusion is at best de minimis, indeed infinitesimal, and insufficient;” a survey revealing a less than 3% rate of confusion was insufficient to show a likelihood of confusion .); *SeealsoCumberland Packing Corp. v. Monsanto Co.,* 140 F.Supp.2d 241, 254 (E.D.N.Y.2001) (a survey showing a 7.84% confusion rate found to be insufficient to raise a material fact as to the likelihood of confusion). The plaintiff should be able to demonstrate a reasonable likelihood that reasonable people will be confused.

***4** [5] The sixth factor regarding good faith adoption of the mark also favors defendants. The relevant intent in this inquiry is whether the alleged infringer intended “to palm off his products as those of another.”*SeeMiss Universe, Inc. v. Patricelli,* 408 F.2d 506, 509 (2d Cir.1969); *SeealsoMaternally Yours, Inc. v. your Maternity Shop, Inc.,* 234 F.2d 538, 542 (2d Cir.1956). In the present case, there is no evidence that defendants intended to confuse the public. There is no basis to argue that the Ralph Nader political ad which has the clear intent to criticize other political candidates who accept money from wealthy contributors, at the same time, attempts or intends to imply that he is a political candidate endorsed by MasterCard. There is uncontradicted testimony that neither Ralph Nader, nor his committees, had any such intent. (Nader Aff. ¶ 21; Zopoth Aff. ¶ 7, Ex. 16).

[6] The seventh factor, the quality of defendants' products or services, is of insignificant weight in this case. There is no reasonable comparison to be made between the quality of the products and services provided by MasterCard and the value of defendants' politics. MasterCard provides a quality of financial services which can readily be compared to its commercial competitors. However, it is purely the public's subjective opinion of the appeal and attractiveness of a political candidate's ideas and record which determines whether the public will buy the politics any candidate for office is selling.

[7] The eighth and final factor to be weighed is the level of consumer sophistication in either of the relevant markets for credit card services or for political candidates. Unless otherwise demonstrated, it is reasonable to conclude that the general American public is sophisticated enough to distinguish a Political Ad from a commercial advertisement. Rarely, if ever, is there a realistic opportunity to confuse the two. Indeed, as previously discussed, out of the 452 e-mails received by MasterCard regarding Ralph Nader's Political Ad, only 2-3 questioned MasterCard's involvement with Ralph Nader's campaign. This sampling of American con-

sumers, which is the only proof offered on the record, is a sufficient indication that consumers are generally sophisticated enough to decipher between MasterCard's commercial purposes and Ralph Nader's political agenda.

When balancing the eight *Polaroid* factors, no one factor can determine the ultimate issue of likelihood of confusion to the consumer. *See*W.W.W. Pharm. Co. v. The Gillette Co., 808 F.Supp. 1013, 1022 (S.D.N.Y.1992), *aff'd*,984 F.2d 567 (2d Cir.1993). To properly weigh these factors requires the court to view each factor in light of the totality of the evidence. *Id.* Thus, after balancing the *Polaroid* factors, this Court finds that there is no genuine issue of material fact with regard to any likelihood of confusion between MasterCard's Priceless Advertisements and Ralph Nader's Political Ad which could constitute a violation of the Trademark Act. Defendants' summary judgment motion to dismiss Counts One and Two of plaintiff's complaint is therefore granted.

***5** MasterCard also alleges a state law claim under New York common law for trademark infringement in Count Seven of the complaint. Under New York common law, as is required under federal law, a plaintiff must show a likelihood of confusion between the two products in order to prevail. *See*Nabisco v. Warner-Lambert Co. ., 32 F.Supp.2d 690, 701 (S.D.N.Y.1999). As with plaintiff's federal Lanham Act claims, there is no likelihood of confusion between MasterCard's Priceless Ads and Ralph Nader's Political Ad. As a matter of law, plaintiff has failed to show a genuine issue of material fact as to the existence of a likelihood of confusion between MasterCard's financial services and Ralph Nader's 2000 presidential political campaign. Therefore, defendants are granted summary judgment on plaintiff's New York common law trademark infringement claim in Count Seven of the complaint.

2. *Unfair Competition and Misappropriation*

[8] In its fifth and sixth counts, MasterCard alleges state law claims under New York common law for unfair competition and misappropriation. Under Section 301(a) of the Copyright Act, 17 U.S.C. § 301(a), all legal or equitable state rights that are equivalent to any of the exclusive rights granted within the general scope and subject matter of the Copyright Act are preempted by the Copyright Act. Courts have used a two-part test to determine whether a state cause of action will be preempted by the Copyright Act: (1) what is the nature of the work in question; and (2) what are the rights claimed in that work under state law. *See*Harper & Row, Publishers, Inc. v. Nations Enters., 501 F.Supp. 848, 850 (S.D.N.Y.1980), *aff'd.*723 F.2d 195 (2d Cir.1983), *rev'd on other grounds*,471 U.S. 539, 105 S.Ct. 2218, 85 L.Ed.2d 588 (1985); *See*alsoMayer v. Josiah Wedgwood & Sons, Ltd., 601 F.Supp. 1523, 1532 (S.D.N.Y.1985).

The first prong for preemption is met when the nature of the work protected comes within the subject matter of copyright as defined by § § 102 and 103 of the Copyright Act. *See*§ 301(b)(1). Because MasterCard owns copyright registrations for several of its "Priceless" television advertisements, and because "advertisements are generally capable of receiving copyright protection,"*Raffoler, Ltd. v. Peabody & Wright, Ltd.*, 671 F.Supp. 947, 950 (E.D.N.Y.1987), MasterCard's advertisements clearly fall within the subject matter of the Copyright Act.

The second prong for preemption is met when the right granted under state law is "equivalent to any of the exclusive rights within the general scope of copyright as specified in Section 106."17 U.S.C. § 301(a).*See*alsoHarper, 501 F.Supp. at 850;*Mayer*, 601 F.Supp. at 1532. The federal rights granted by the Copyright Act include the right "to prepare derivative works based upon the copyrighted work."17 U.S.C. § 106. As evident in the Complaint, MasterCard claims that the Nader Ad violated MasterCard's rights because it was derived form MasterCard's "Priceless" advertising.

(Compl.¶ 50). The Second Circuit Court of Appeals has held that misappropriation and unfair competition claims "grounded solely in the copying of plaintiff's protected expression are deemed preempted by Section 301."*Computer Assocs. Int'l, Inc. v. Altai, Inc.*, 982 F.2d 693, 717 (2d Cir.1992) (citations omitted); *Seealso**American Movie Calssics Co. v. Turner Entm't Co.*, 922 F.Supp. 926, 933 (S.D.N.Y.1996). Thus, Counts Five and Six are dismissed on defendants' motion for summary judgment as those claims are preempted by federal copyright law.

***6** [9] In pleading its sixth count, along with its misappropriation claim, MasterCard also alleges the state law violation of "palming off" by defendants. (Compl.¶ 62). "Palming off" or passing off, "occurs when a producer misrepresents his own goods or services as someone else's."*Dastar Corporation v. Twentieth Century Fox Film Corporation, et al.*, 539 U.S. 23, 123 S.Ct. 2041, 2045, n. 1, 156 L.Ed.2d 18 (2003). Lack of likely consumer confusion is independently sufficient to defeat a claim of palming off. *See**Towle Mfg. Co. v. Godinger Silver Art Co., Ltd.*, 612 F.Supp. 986, 995-96 (S.D.N.Y.1985). Therefore, this claim also fails for the same reason MasterCard's trademark infringement claim fails: there is no likelihood of confusion as a matter of law. Dismissal of Count Six is therefore warranted on this basis as well.

3. *Dilution*

Counts Three and Eight of plaintiff's complaint allege against defendants federal and state dilution of plaintiff's trademarks. The Federal Trademark Dilution Act, 15 U.S.C. § 1125(c) and the New York anti-dilution law, New York Gen. Bus. Law § 360-1, protect against the unauthorized use of marks that impairs the goodwill and value of plaintiff's mark. "Dilution" is defined as "the lessening of the capacity of a famous mark to identify and distinguish goods or services, regardless of (1) competition between the owner of the famous mark and other parties, or (2) likelihood of confusion, mistake, or deception."15 U.S.C. § 1127. Section 1125(c) provides that the owner of a famous mark is entitled to an injunction against another person's "commercial use in commerce of a mark if such use begins after the mark or trade name has become famous and causes dilution of the distinctive quality of the mark."Under federal law, the elements for a claim of dilution are that "1) plaintiff's mark is famous; 2) it is inherently distinctive; 3) defendant's use of the junior mark is a commercial use in commerce; 4) defendant's use began after plaintiff's mark became famous; and 5) defendant's use of the junior mark causes dilution of the distinctive quality of the plaintiff's mark."*Playtex Products, Inc. v. Georgia-Pacific, Inc., et al.*, 2003 WL 21939706, 8 (S.D.N.Y.2003). Moreover, a plaintiff must show "actual dilution, rather than a likelihood of dilution."*Moseley, et al. v. V Secret Catalogue, Inc., et al.*, 537 U.S. 418, 433, 123 S.Ct. 1115, 155 L.Ed.2d 1 (2003). Under both federal and New York law, dilution can involve either blurring or tarnishment.*New York Stock Exchange, Inc., v. New York, New York Hotel, LLC*, 293 F.3d 550, 557 (2d Cir.2002); *Seealso**Perkins School for the Blind v. Maxi-Aids, Inc., et al.*, 274 F.Supp.2d 319, 325 (E.D.N.Y.2003); *World Wrestling Federation Entertainment, Inc. v. Bozelli*, 142 F.Supp.2d 514, 529 (S.D.N.Y.2001).

Blurring has typically involved "the whittling away of an established trademark's selling power through its unauthorized use by others upon dissimilar products."*Mead Data Central, Inc. v. Toyota Motor Sales, U.S.A., Inc.*, 875 F.2d 1026, 1031 (2d Cir.1989) (describing such " 'hypothetical anomalies' as 'Dupont shoes, Buick aspirin tablets, Schlitz varnish, Kodak pianos, Bulova gowns, and so forth" ') (quoting legislative history of section 368-d) (citation omitted). That is, trademark dilution statutes are designed to cover those situations where the public knows that the defendant is not connected to or sponsored by the plaintiff, but the ability of the plaintiff's mark to serve as a unique identifier of the plaintiff's goods or services is weakened because the relevant public now also as-

sociates that designation with a new and different source. *See*Federal Express Corp. v. Federal Espresso, Inc., 201 F.3d 168, 174 (2d Cir.2000) (quoting *Sports Authority, Inc. v. Prime Hospitality Corp.*, 89 F.3d at 965-66 (discussing New York law) (internal quotation marks and brackets omitted).

***7** In *New York Stock Exchange*, the Second Circuit held that blurring occurs when " 'the defendant uses or modifies the plaintiff's trademark to identify the defendant's goods or services, raising the possibility that the mark will lose its ability to serve as a unique identifier of the plaintiff's product. To determine the likelihood of blurring, [courts] have looked to six factors, including: (i) the similarity of the marks; (ii) the similarity of the products covered; (iii) the sophistication of the consumers; (iv) the existence of predatory intent; (v) the renown of the senior mark; and (vi) the renown of the junior mark."*New York Stock Exchange, Inc., v. New York, New York Hotel, LLC,* 293 F.3d 550, 558 (2d Cir.2002) (citing *Deere & Co. v. MTD Prods., Inc.*, 41 F.3d 39, 43 (2d Cir.1994)); *See also*Katz, et al. v. Modiri, et al., 283 F.Supp.2d 883, 901 (S.D.N.Y.2003).

Tarnishment occurs when the plaintiff's mark is " 'linked to products of shoddy quality, or is portrayed in an unwholesome or unsavory context,' with the end result that 'the public will associate the lack of quality or lack of prestige in the defendant's goods with the plaintiff's unrelated goods." ' *Id.* "The sine qua non of tarnishment is a finding that the plaintiff's mark will suffer negative associations through defendant's use." *Hormel Foods Corp. v. Jim Henson Productions, Inc.*, 73 F.3d 497, 507 (2d Cir.1996).

The Federal Trademark Dilution Act specifically exempts noncommercial uses of a mark from its coverage. Section 1125(c)(4) provides that "[t]he following shall not be actionable under this section: ... (B) Noncommercial use of a mark."Therefore, prior to even addressing whether defendants have actually diluted plaintiff's marks under the federal law, the Court must first determine whether defendants' use of the marks is "commercial," and thereby, whether that use is even covered by the statute.[FN1]

FN1. Black's Law Dictionary defines 'commercial' as "Relates to or is connected with trade and traffic or commerce in general; is occupied with business and commerce. Generic term for most all aspects of buying and selling."

The Lanham Act defines 'use in commerce' as the "use of a mark in the ordinary course of trade ... For purposes of this chapter, a mark shall be deemed to be in use in commerce-(1) on goods when-(A) it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto, or if the nature of the goods makes such placement impracticable, then on documents associated with the goods or their sale, and (B) the goods are sold or transported in commerce, and (2) on services when it is used or displayed in the sale or advertising of services and the services are rendered in commerce, or the services are rendered in more than one State or in the United States and a foreign country and the person rendering the services is engaged in commerce in connection with the services."15 U.S.C. § 1127.

[10] Plaintiff argues that Ralph Nader's Political Ad is commercial in nature even though it neither sells products or services, is not designed to entice consumers to buy products or services, and does not propose any kind of commercial transaction. MasterCard asserts that contributions to the Nader 2000 General Committee "increased from $5125 before the Ad ran to $818,000 in August 2000, after the Ad ran through the "DONATE ON-LINE" icon *orotherwise."*(Pl's. Mem. in Opp. to Summ. J. 26) (emphasis added). Although the Nader Ad ran before a large sum of contributions were made to his

campaign, plaintiff offers no evidence of a causal connection between the Ad and the contributions. There is nothing in the record other than the inference to be drawn from the proximity in time that advances the notion that the contributions Ralph Nader and his political committee received were a direct result of the Ad.

Even assuming the Nader Ad caused greater contributions to be made to his political campaign, this would not be enough to deem Ralph Nader's Ad "commercial." If so, then presumably, as suggested by defendants, all political campaign speech would also be "commercial speech" since all political candidates collect contributions. Ralph Nader's Political Ad attempts to communicate that other presidential candidates can be bought, but that the "truth," represented by himself, cannot. The Nader Ad is a strong political message which expresses his personal opinion on presidential campaigning. The legislative history of the Lanham Act clearly indicates that Congress did not intend for the Act to chill political speech. In speaking about the amendments to Section 43(a) that expanded what was actionable as deceptive advertisements, one of the new law's sponsors, United States Representative Robert Kastenmeier, pointed out that political advertising and promotion are not meant to be covered by the term "commercial." He stated that the statute

***8** uses the word "commercial" to describe advertising or promotion for business purposes, whether conducted by for-profit or non-profit organizations or individuals. *Political advertising and promotion is political speech, and therefore not encompassed by the term "commercial."*This is true whether what is being promoted is an individual candidacy for public office, or a particular political issue or point of view ...

134 Cong. Rec. H. 1297 (daily ed. April 13, 1989) (statement of Wisconsin Rep. Kastenmeier) (emphasis added).

Plaintiff MasterCard urges the Court to rely on *United We Stand America, Inc. v. United We Stand, America New York, Inc.*, 128 F.3d 86 (2d Cir.1997) to conclude that Ralph Nader's activities are "commercial" in nature. That case is not instructive in determining whether or not MasterCard has a basis to bring a claim against defendants under the Federal Trademark Dilution Act. In *United We Stand*, the Court was determining whether a certain political activity fell under the scope and the meaning of the word "services" and "use in commerce" of the Lanham Trademark Act, § 32(1)(a), 15 U.S.C.A. § 1114(1)(a).[FN2] That particular section of the Lanham Act does not have a commercial activity requirement, nor does it exempt from liability noncommercial use of a mark. *See**Planned Parenthood Federation of America Inc. v. U.S. District Court Southern District of New York*, 42 U.S.P.Q.2d 1430, 1434 (S.D.N.Y.1997). However, the Federal Trademark Dilution Act, 15 U.S.C.A. § 1125(c), specifically exempts from the scope of all provisions of Section 1125 the "noncommercial use of a mark." *See**Id.*, at 1433.

> FN2."Any person who shall, without the consent of the registrant use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered trademark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive, shall be liable in a civil action by the registrant for the remedies hereinafter provided ."15 U.S.C.A. § 1114(1)(a).

Though not binding, this Court finds the analysis in *American Family Life Insurance Company v. Hagan, et al.*, 266 F.Supp.2d 682 (N.D.Ohio 2002), to be relevant and persuasive. In that case, similar to the case at hand, the plaintiff, American Family Life Insurance Company, or AFLAC, ran well-known "AFLAC Duck" commercials which featured a white duck quacking the company's name "AFLAC." *Id.*, at 684.One of the defendants was a candidate for Governor of the State of Ohio running

against the incumbent Governor Robert Taft. The candidate and his Campaign, developed internet commercials that " 'borrow[ed]' from AFLAC's commercials. Specifically, the internet commercials include[d] a crudely animated character made up of the incumbent Governor's head sitting on the body of a white cartoon duck; the duck quacks 'TaftQuack' several times during each commercial," which defendants ran on their website, www.taftquack.com. *Id.*Defendants' website also contained a link which visitors could use to make campaign contributions. *Id.* at 686-87.Among other claims, plaintiff sued defendants for federal trademark dilution and moved for a preliminary injunction.

In denying the plaintiff's motion for a preliminary injunction, and finding that the plaintiff was not likely to prevail on its dilution claim, the court also found that defendants' speech was political, rather than commercial. Specifically, the court stated that the candidate was "using a quacking cartoon character, which admittedly brings to mind AFLAC's marks, *as part of his communicative message*, in the context of expressing political speech."*Id.*, at 700 (emphasis in original). The court added that though "the consuming public may associate the AFLAC Duck and the TaftQuack character-a proposition the Court accepts-[this] is an insufficient predicate to support injunctive relief of political speech."*Id.*, at 701.The court further noted that though defendants included in their website a mechanism for visitors to make campaign contributions, "it is arguable whether [the candidate's] speech proposes a commercial transaction at all."*Id* ., at 697.The court stated that defendants' solicitation of contributions, and the resulting making of contributions, "is much more than merely a commercial transaction. Indeed, this exchange is properly classified not as a commercial transaction at all, but completely noncommercial, political speech."*Id.*

***9** [11] This Court finds that Ralph Nader's use of plaintiff's trademarks is not commercial, but instead political in nature and that therefore, it is exempted from coverage by the Federal Trademark Dilution Act. However, even if Ralph Nader's use of plaintiff's trademarks could be deemed commercial in nature, such use did not dilute plaintiff's marks. Defendants do not dispute that plaintiff's marks are famous, distinctive, or that they used plaintiff's marks after such marks became famous. However, there is no evidence in the record that defendants' use of plaintiff's marks actually caused dilution of the distinctiveness of plaintiff's marks. Plaintiff does not offer evidence that defendants' limited use of the Priceless marks lessened its value or the capacity of these marks to identify and distinguish plaintiff's goods or services. Further, plaintiff does not claim, nor is there any evidence in the record, that due to defendant's use of plaintiff's marks, plaintiff altered or lessened its use of the marks to identify MasterCard's products or services.

Count Three of plaintiff's complaint alleging dilution of plaintiff's trademarks is dismissed on defendants' motion for summary judgment. Ralph Nader's use of plaintiff's trademarks is political in nature, not within a commercial context, and is therefore exempted from coverage by the Federal Trademark Dilution Act. Furthermore, there is no evidence on the record that Ralph Nader's use of plaintiff's trademarks diluted plaintiff's trademarks.

[12] Count Eight, alleging dilution of MasterCard's trademarks under state law, is based on N.Y.G.B.L. § 360-1. Section 360-1 provides that "[l]ikelihood of injury to business reputation or of dilution of the distinctive quality of a mark or trade name shall be a ground for injunctive relief in cases of infringement of a mark registered or not registered or in cases of unfair competition, notwithstanding the absence of competition between the parties or the absence of confusion as to the source of goods or services."In order to show state trademark dilution under section 360-1, MasterCard must demonstrate that it's "trademark is of truly distinctive quality or has acquired secondary meaning, and, second, that there is a 'likelihood of dilution." ' *Brennan's, Inc.*

v. Brennan's Restaurant, LLC, et al., 2003 WL 1338681, 6 (S.D.N.Y.2003) (citing *Deere & Co. v. MTD Prods., Inc.*, 41 F.3d 39, 42 (2d Cir.1994)).

Again, it is not in dispute that plaintiff's marks are of a distinctive quality, and have acquired secondary meaning. Yet, there is no evidence on the record that defendants' use of plaintiff's marks created even a likelihood of dilution of such marks. There is no evidence that defendants' limited and political use of plaintiff's marks could weaken those marks' ability to serve as a unique identifier of plaintiff's goods or services. Therefore, there is no evidence of possible dilution by "blurring." Further, there is no evidence that plaintiff's marks could be tarnished or suffer from negative associations in the eyes of the public due to defendants' use of those marks. Therefore, there is no evidence of dilution of plaintiff's marks by tarnishment. As with plaintiff's federal dilution claim, summary judgment for defendants on plaintiff's Count Eight alleging state law dilution of plaintiff's trademarks is hereby granted.

4. *Copyright Infringment*

***10** [13] In Count Four, plaintiff alleges copyright infringement of its Priceless Advertisements. In response, defendants argue the Nader Ad is a fair use of the Priceless Advertisements because it is a parody of the Priceless Advertisements.

"From the infancy of copyright protection," the fair use doctrine "has been thought necessary to fulfill copyright's very purpose, '[t]o promote the Progress of Science and useful Arts." ' *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 575, 114 S.Ct. 1164, 127 L.Ed.2d 500 (1994) (quoting U.S. Const., art. I, § 8, cl. 8). In *Campbell*, defendants Luther R. Campbell, Christopher Wongwon, Mark Ross, and David Hobbs, collectively known as 2 Live Crew, a rap music group, created a song entitled "Pretty Woman" that parodied Roy Orbison's copyrighted song, "Oh, Pretty Woman." *Id.*, at 571-72.Plaintiff Acuff-Rose Music, Inc., who owned the rights to Orbison's song, sued defendants for copyright infringement. *Id.*, at 573.The District Court for the Middle District of Tennessee granted summary judgment in favor of defendants, finding that 2 Live Crew's song was a fair use parody of the Orbison song and that the commercial purpose of 2 Live Crew's song was not a bar to a finding of fair use. *Id.* The Court of Appeals for the Sixth Circuit reversed, holding that a finding of fair use was barred by the song's commercial character and excessive borrowing of the Orbison song. *Id.*, at 573-74.In reversing the Court of Appeals' decision, the United States Supreme Court held that a parody's commercial nature is not a bar to a finding of fair use and is in fact only one element to be considered in a fair use analysis. It held that the Court of Appeals gave insufficient consideration to the nature of a parody in assessing the degree to which a parody copies. *Id.*, at 572, 594.

As noted in *Campbell*,"in truth, in literature, in science and art, there are, and can be, few, if any, things, which in an abstract sense, are strictly new and original throughout. Every book in literature, science and art, borrows, and must necessarily borrow, and use much which was well known and used before."*Id.* (quotation marks omitted). Until the 1976 Copyright Act, the doctrine of fair use grew exclusively out of the common law. *See Id.*, at 576;*Folsom v. Marsh*, 9 F.Cas 342, 348 (C.D.Mass.1900) (CCD Mass. 1841) (Story, J.) (Stating fair use test). With the Copyright Act, Congress restated the common law tradition of fair use. The statute provides that the use or reproduction of a copyrighted work is "not an infringement of copyright" if it is used "for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research."17 U.S.C.A. § 107. In determining whether the work has been used for such a purpose, the statute lists four nonexclusive factors to consider: 1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; 2) the nature of the copyrighted work; 3) the amount and substantiality

of the portion used; and 4) the effect of the use upon the potential market for, or value of, the copyrighted work. 17 U.S.C. § 107(1)-(4). It has been found that "once a work is determined to be a parody, the second, third, and fourth factors are unlikely to militate against a finding of fair use."*Abilene Music, Inc., et al. v. Sony Music Entertainment, Inc., et al.*, 2003 WL 21415311, 4 (S.D.N.Y.2003).

***11** This section of the Copyright Act "intended that courts continue the common law tradition of fair use adjudication" and "permits and requires courts to avoid rigid application of the copyright statute, when, on occasion, it would stifle the very creativity which that law is designed to foster."*Campbell*, 510 U.S. at 577 (quotation marks omitted). Fair use analysis, therefore, always "calls for case-by-case analysis." *Id.* The fair use examples provided in § 107 are "illustrative and not limitative" and "provide only general guidance about the sorts of copying that courts and Congress most commonly had found to be fair uses."*Id.*;*SeeNimmer* § 13.05 [A}, at 13-153 ("[T]he factors contained in Section 107 are merely by way of example, and are not an exhaustive enumeration."). The ultimate test of fair use, therefore, is whether the copyright law's goal of "promot[ing] the Progress of Science and useful Arts,"U.S. Const., art. I, § 8, cl., 8, "would be better served by allowing the use than by preventing it."*Arica Inst., Inc. v. Palmer*, 970 F.2d 1067, 1077 (2d Cir.1992) (quoting *Peter Pan Fabrics, Inc. v. Martin Weiner Corp.*, 274 F.2d 487, 589 (2d Cir.1960) (L.Hand, J.)). The burden of proof is on the defendants to demonstrate fair use.*Infinity Broadcast Corp. v. Kirkwood*, 150 F.3d 104, 107 (2d Cir.1998). Though recognizing that fair use is a "mixed question of law and fact," courts regularly resolve fair use issues at the summary judgment stage where there are no genuine issues of material fact. *Castle Rock Entertainment, Inc. v.Carol Publishing Group, Inc.* 150 F.3d 132, 136 (2d. Cir.1998).

Before considering these factors in detail, it is important to note the difference between an advertisement that promotes a parody of a copyrighted work and an advertisement that itself actually infringes a copyright. An advertisement which uses elements of a copyrighted work "does not necessarily ... [infringe] the copyright, if the product that it advertises constitutes a fair use of the copyrighted work."*Steinberg v. Columbia-Delphi Productions*, 663 F.Supp. 706, 714 (S.D.N.Y.1987) (citing *Warner Bros. v. American Broadcasting Cos.*, 720 F.2d 231, 242-44 (2d. Cir.1983) (finding that promotional broadcasts for a television series legally parodying the Superman comic strip character did not infringe copyright in Superman character)). On the other hand, an advertisement infringes a copyright when what is being advertised "bears no relationship to the copyrighted work."*Steinberg*, 663 F.Supp. at 714. In such a case, "[n]o matter how well known a copyrighted phrase becomes, its author is entitled to guard against its appropriation to promote the sale of commercial products."*Id.* (citing *Warner Bros.*, 720 F.2d at 242). However, even a wholly commercial advertisement may itself constitute a fair use. *Leibovitz v. Paramount Pictures Corp.*, 137 F.3d 109 (2d Cir.1998) (finding a poster of a pregnant Leslie Nielson, used to advertise "Naked Gun 33 1/3," to be a fair use of the photograph of Demi Moore it parodied).

***12** The first fair use factor to consider is "the purpose and character of the [allegedly infringing] use, including whether such use is of a commercial nature or is for nonprofit educational purposes."17 U.S.C. § 107(1). As this Court has already discussed, the Ralph Nader Political Ad's use is not commercial. The stated purpose of the defendants' advertisement was to raise public awareness of Ralph Nader's desire to be included in the upcoming, televised Presidential candidate debates. (Nader Aff. ¶ 14; Amato Aff. ¶ 11; Exs. 12-15). The Nader Ad depicted that the two major party candidates were beholden to special interests, which was the reason that Ralph Nader, who was not so beholden, should be included in the debates. (Defs.' Mem. in Supp. of Summ. J. 26).

The more important question under the first factor, and in fair use analysis generally, is whether the allegedly infringing work "merely supersedes" the original work "or instead adds something new, with a further purpose or different character, altering the first with new expression, meaning or message,"*Campbell,* 510 U .S. at 579, in other words "whether and to what extent the new work is 'transformative." ' *Id.,* at 579 (quoting Leval, *Toward a Fair Use Standard,* 103 Harv.L.Rev. 1105, 1111 (1990)). If "the secondary use adds value to the original-if [copyrightable expression in the original work] is used as raw material, transformed in the creation of new information, new aesthetics, new insights and understandings-this is the very type of activity that the fair use doctrine intends to protect for the enrichment of society." *Id.* As stated in *Campbell,* the goal of copyright "is generally furthered by the creation of transformative works." *Id.,* at 579.

One such transformative use that is typically found to be fair use is a parody. Defendants' argument that Ralph Nader's Political Ad is transformative of MasterCard's Priceless Advertisements is as follows: Defendants believe that the MasterCard commercials' underlying message is "that MasterCard is the best way to pay for everything that matters."(Defs' Mem in Supp. for Summ. J. 27). The Nader Ad, on the other hand, portrays the cold, big-money arena of Presidential polities and contrasts Ralph Nader's "truth" as the remedy for the bought and paid-for positions of others. Through this message, defendants claim that the Nader Ad "lays bare the artifice of the original, which cloaks its materialistic message in warm, sugar-coated imagery that purports to elevate intangible values over the monetary values it in fact hawks" through parody (Defs' Mem. in Supp. of Summ. J. 27).

Parody has an obvious claim to transformative value. *See**Campbell,* 510 U.S. at 577. A parody is characterized by an attempt to mimic an original, expressive, and usually famous work. *See**Id.,* at 586 ("parodies invariably copy publicly known, expressive works"). Focusing particularly on the fair use protection to which parodies are entitled, the Court in *Campbell* initially noted that "parody may or may not be fair use,"*Id.,* at 581, and "like any other use, has to work its way through the relevant factors, and be judged case by case, in light of the ends of the copyright law,"*Id.*The Court went on to say, "[T]he heart of any parodist's claim to quote from existing material is the use of some elements of a prior author's composition to create a new one that, at least in part, comments on that author's works."*Id.,* at 580.The comment must have some "critical bearing on the substance or style of the original composition."*Id.* The relevant inquiry is "whether a parodic character *may reasonably be perceived."Id.* (emphasis added).

***13** Plaintiff claims that because there is nothing in the Nader Ad which "comments on or refers to MasterCard or its Priceless Ads" (Pl.'s Mem. in Opp'n to Summ. J. 11), it cannot be classified as a parody. However, the Supreme Court in *Campbell* stated "[p]arody serves its goals whether labeled or not, and there is no reason to require parody to state the obvious (or even the reasonably perceived)."*Id.,* n. 17. The Court also added, "[w]hile we might not assign a high rank to the parodic element here, we think it fair to say that [defendant's] song reasonably could be perceived as commenting on the original or criticizing it, to some degree."*Id.,* at 583.In fact, the Court declined to evaluate the parody, stating that "[t]he threshold question when fair use is raised in defense of parody is whether the parodic character may reasonably be perceived. Whether, going beyond that, parody is in good taste or bad does not and should not matter to fair use."*Id.,* at 582.In finding a parodic element in defendant's infringement of plaintiff's song, the Court also commented that the defendants in that case would have even more easily met the requirement had there been less risk of "market substitution" of the parody for the original:

A parody that more loosely targets an original than the parody presented here may still be sufficiently

aimed at an original work to come within our analysis of parody. If a parody whose wide dissemination in the market runs the risk of serving as a substitute for the original ..., it is more incumbent on one claiming fair use to establish the extent of transformation and the parody's critical relationship to the original. By contrast, when there is little or no risk of market substitution, whether because of the large extent of transformation of the earlier work, the new work's minimal distribution in the market, the small extent to which it borrows from the original, or other factors, taking parodic aim at an original is a less critical factor in the analysis, and looser forms of parody may be found to be fair use ...

Campbell, 510 U.S. at 580, n. 14.

Where, as here, the parody really has no demonstrative capacity to divert sales from the original, as was stated in *Campbell,* a showing of "the parody's critical relationship to the original" is less vital in the fair use analysis.

The Nader Ad does add something new and qualifies as a "transformative" work. Whether it "comments" on the original is the issue in question. MasterCard's message depicted in its Priceless Advertisements is very plain and straightforward. In a series of advertisements, MasterCard presents various intangible moments that are highly valuable, yet unable to be "purchased" or are "priceless." Hence, "there are some things that money can't buy."[FN3] This idea is followed by the message, that the viewer-consumer can purchase everything else with their MasterCard credit card-"for everything else, there's MasterCard." Ralph Nader's Political Ad attempts to show various ways different Presidential candidates can be bought in the "big-money arena of Presidential politics" (Def's Mem. in Supp. Summ. J. 27) and contrasts the "priceless" truth represented by Ralph Nader as the remedy for the bought and paid for positions of others. Through this depiction, Ralph Nader argues that he not only sends across his own message, but that he wittingly comments on the craft of the original, "which cloaks its materialistic message in warm, sugar-coated imagery that purports to elevate intangible values over the monetary values it in fact hawks."*Id.* This commentary "may reasonably be perceived." The message need not be popular nor agreed with. It may be subtle rather than obvious. It need only be reasonably perceived. Ralph Nader's Political Ad is sufficiently a parody for the purposes of a fair use analysis, and consequently, is transformative.

> FN3. It should be noted that with regard to the phrase "there are some things that money can't buy," not even MasterCard claims that phrase is its original creation.

***14** The second statutory factor, "the nature of the copyrighted work,"§ 107(2), relates to whether the original work is " 'creative' as opposed to 'factual,' as well as to whether the work has been previously published."*Feiner v. H.R. Industries,* 10 F .Supp.2d 310, 314 (S.D.N.Y.1998). Original works that are creative in nature will generally receive greater copyright protection. *Seee.g.Ringgold v. Black Entertainment Television, Inc.,* 126 F.3d 70, 80 (2d Cir.1997). A previously published work available to the general public will receive less protection under the fair use doctrine than an unpublished work which has not yet been released to the general public by its author. *Feiner,* 10 F.Supp.2d at 314;*Arica Institute, Inc. v. Palmer,* 970 F.2d 1067, 1078 (2d Cir.1992).

The creative nature of plaintiff's Priceless Advertisements places these advertisements in the "core of intended copyright protection." *Campbell,* 510 U.S. at 586. Although this seems to favor plaintiff, courts have recognized that "this factor may be of less (or even of no) importance when assessed in the context of certain transformative uses."*Castle Rock Entertainment, Inc. v. Carol Publishing Group, Inc.,* 150 F.3d 132, 144 (2d Cir.1998); *SeealsoLeibovitz v. Paramount Pictures Corporation,* 2000 WL 1010830, 4 (S.D.N.Y.2000) ("It is well established that the second factor-the nature of the copyrighted work-is not very important to the

fair use analysis."); *Abilene Music, Inc., et al. v. Sony Music Entertainment, Inc., et al.*, 2003 WL 21415311, 4 (S.D.N.Y.2003) ("the second factor, the nature of the original work, is not heavily weighted in cases involving parodies"). In particular, giving this factor undue weight in a fair use analysis would prevent findings of fair uses which advance science and art through criticism or commentary. *Seee.g.Campbell,* 510 U.S. at 586 (finding second factor unlikely to "help in separating the fair use sheep from the infringing goats in a parody case since parodies almost invariably copy publicly known, expressive works."). This factor is without much force in most cases, and its relevance here is slight.

In assessing the third factor, the Court must focus on only the protected phrases of the Priceless Advertisements. Further, the amount and substantiality of the portion used in relation to the copyrighted work as a whole must be examined in context to determine whether the extent of the copying is consistent with or more than necessary to further the purpose and character of the use. *SeeCampbell,* 510 U.S. at 586-587. In the parody context, this concerns "what else the parodist did besides go to the heart of the original."*Liebowitz v. Paramount Pictures Corp.*, 137 F.3d 109 (2d Cir.1998) (quoting *Campbell,* 510 U.S. at 589). Although the Ralph Nader Political Ad copied the word "priceless" and the phrase "there are some things money can't buy" and used them in a similar manner, the greater part of the Nader Ad is original-the narration, the supertitles, and the film imagery is rather different from the MasterCard commercials. The substance of the message is different from the message communicated by the advertisement it copies. In order for the Ralph Nader Political Ad to be considered a legitimate parody of the Priceless Advertisement, it necessarily must take enough from MasterCard's advertisement to assure that the viewer will be reminded of the ad that it borrows from.

***15** As outlined in *Leibovitz,* 137 F.3d at 113, the Court in *Campbell* made three important points concerning the third-factor. First, consideration must be given not only to the quantity of the materials taken but also to "their quality and importance" to the original work. *Campbell,* 510 U.S. at 587. Second, "the parody must be able to 'conjure up' at least enough of the original to make the object of its critical wit recognizable."*Id.,* at 588.Third, the court explained that "[o]nce enough has been taken to assure identification, how much more is reasonable will depend, say, on the extent to which the [copying work's] overriding purpose and character is to parody the original or, in contrast, the likelihood that the parody may serve as a market substitute for the original."*Id.* Thus, as the Court in *Campbell* noted, the third factor "enquiry will harken back to the first of the statutory factors,"*Id.,* at 586, with the consideration of the purpose and character of the copying, as well as look to the fourth statutory factor in addressing the potential for market substitution. *Id.,* at 587."That approach leaves the third factor with little, if any, weight against fair use so long as the first and fourth factors favor the parodist."*Liebowitz,* 137 F.3d at 116. As this Court has already found, the first factor is in favor of the defendants in that defendants' use of the Priceless Advertisements is not commercial in nature and is a transformative parody of those advertisements.

The fourth factor looks at "the effect of the use upon the potential market for or value of the copyrighted work."*Campbell,* 510 U.S. at 588. As the *Campbell* opinion explained, if the secondary work harms the market for the original through criticism or parody, rather than by offering a market substitute for the original that supersedes it, it does not produce a harm cognizable under the Copyright Act." *Id.,* at 592.If the secondary copied use offers itself as a market substitute and in that way harms the market value of the original, this factor argues strongly against a finding of fair use. *SeeOn Davis v. The Gap, Inc.*, 246 F.2d 152, 175 (2nd Cir.2001). In this case, the Nader Ad is sufficiently transformative of MasterCard's Priceless Advertisements. The Ralph Nader Political Ad may serve a general

overlapping market, the viewing public. However, it serves an entirely different purpose than the Priceless Advertisements, a political non-commercial purpose. For this reason, the fourth factor also weighs heavily in the defendant's favor for a finding of fair use.

There is no genuine issue of material fact after weighing the factors pertinent to a finding of fair use. The Nader Ad is a non-infringing fair use parody of MasterCard's Priceless Advertisements under Section 107 of the Copyright Act. Accordingly, defendants' motion for summary judgment dismissing Count Four of MasterCard's complaint is granted.[FN4]

> FN4. Defendants also argue that they are entitled to summary judgment on plaintiff's Count Four because the Nader Ad did not copy any "protected expression" from the Priceless Advertisements. Since this Court finds the Nader Ad to be a non-infringing fair use parody of MasterCard's Priceless Advertisements under Section 107 and grants summary judgment in favor of defendants on this basis, it is not necessary for the Court to address this argument.

5. *Deceptive Trade Practices*

***16** [14] In Count Nine, plaintiff claims that through defendants' use of plaintiff's marks in the Nader Ad, defendants intentionally deceived and misled the public in violation of N.Y. Gen. Bus. Law § 349. Defendants argue that plaintiff's Count Nine should be dismissed again because the Nader Ad is political, rather than commercial in nature. Defendants also contend that the requirements of the statute are not met, in that the defendants did not intend to deceive and there is no evidence of actual deception.

Section 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service."N.Y. Gen. Bus. Law § 349(a). In order to establish a claim under Section 349, it must be shown that the defendant committed "a material deceptive act or practice directed to consumers that caused actual harm."*Boule, et al. v. Hutton, et al.*, 328 F.3d 84, 93-94 (2d Cir.2003) (citing *Marcus v. AT & T Corp.*, 138 F.3d 46, 63 (2d Cir.1998)). An act is considered deceptive within the meaning of Section 349 only if it is of such a nature to mislead a reasonable consumer. *Id.* at 94 (citing *Marcus*, 138 F.3d at 64.). Further, in order to prevail on a Section 349 claim, it must be shown that the defendant intentionally deceived consumers. *Eastern American Trio Products, Inc. v. Tang Electronic Corporation, et al.*, 97 F.Supp.2d 295, 423 (S.D.N.Y.2000); *Seealso**Samara Bros., Inc. v. Wal-Mart Stores, Inc.* ., 165 F.3d 120, 131 (2d Cir.1998), *rev'd on other grounds*,529 U.S. 205, 120 S.Ct. 1339, 146 L.Ed.2d 182 (2000).

In the present case, as previously discussed, defendants' use of plaintiff's marks in the Nader Ad is political, not commercial, in nature. The Ad was not being used in connection with the sale or promotion of a product or service, nor in the conduct of business, trade or commerce. There is no evidence the defendants intended to deceive, nor any evidence of actual consumer deception. Both are required showings under Section 349. Therefore, MasterCard's Count Nine is dismissed and defendants' motion for summary judgment on this count is granted.

CONCLUSION

For the foregoing reasons, defendants' motion for summary judgment is hereby GRANTED in its entirety.

S.D.N.Y.,2004.
MasterCard Intern. Inc. v. Nader 2000 Primary Committee, Inc.
Not Reported in F.Supp.2d, 2004 WL 434404 (S.D.N.Y.), 2004 Copr.L.Dec. P 28,781, 70 U.S.P.Q.2d 1046

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APPENDIX 7

H

Eazypower Corp. v. Alden Corp.
N.D.Ill.,2003.
Only the Westlaw citation is currently available.

United States District Court,N.D. Illinois, Eastern Division.

EAZYPOWER CORPORATION, an Illinois corporation, Plaintiff,
v.
ALDEN CORPORATION, a Connecticut corporation, Defendant.

No. 03 C 3164.

Dec. 2, 2003.

Robert B. Breisblatt, Kara Eve Foster Cenar, Joseph Eben Cwik, Philip Dale Segrest, Jr., Welsh & Katz, Ltd., Lee F. Grossman, Eric P Martin, Grossman & Flight, LLC, Chicago, IL, for Plaintiff.
Jeffrey Edward Schiller, Michael Daehyun Lee, Schuyler, Roche & Zwirner, Chicago, IL, Wm Tucker Griffith, John C Linderman, McCormick, Paulding & Huber, LLP, Hartford, CT, for Defendant.

MEMORANDUM, OPINION AND ORDER

ANDERSEN, J.

***1** This case is before the Court on Alden Corporation's motion to dismiss Eazypower's complaint. For the following reasons, the motion to dismiss is denied.

BACKGROUND

Eazypower Corporation is a manufacturing company that sells screwdriver tips and related power tool accessories. One of its products is a broken screw remover set (the "Screw Remover Set"), which is used to remove broken or worn out screws. On or about April 4, 2000, Alden Corporation filed a patent application with the United States Patent and Trademark Office (the "Patent Office") for a screwdriver bit, which is used to remove damaged screws. Alden's patent application was published on October 4, 2001, and the Patent Office allowed the patent on March 19, 2003. At that time, Alden began to send notice letters to potential infringers. However, Alden's patent did not issue until July 22, 2003.

On or about April 4, 2003, Alden sent a letter to Eazypower which stated that Alden had a pending patent that had been "allowed" by the Patent Office and that the soon-to-be-issued patent "will be infringed by, or contributorily infringed by" Eazypower's Screw Remover Set. About ten days later on April 14, 2003, Eazypower received a second letter from Alden that reiterated the infringement allegations and referenced the patent application as number 20010026737.

Eazypower responded to Alden's letter on or about April 23, 2003, in which Eazypower denied the alleged infringement and asserted that the allegations appeared to be baseless, made in bad faith and violated unfair competition law. Despite Alden's assurances that it would not contact any of Eazypower's customers, Ace Hardware, one of Eazypower's customers, did in fact receive a similar cease and desist letter from Alden. As a result, Eazypower corresponded with Alden again on or about April 30, 2003 and demanded that Alden cease writing letters to Eazypower's customers, alleging that Eazypower's Screw Remover Set infringes or contributorily infringes Alden's not-yet-issued patent. At that time, Eazypower also requested information from Alden about the patent claims and how Eazypower's Screw Remover Set allegedly infringed the patent. Alden responded that it needed Eazypower's production drawings in order to determine how the Screw Remover Set infringed Alden's anticipated patent.

On May 12, 2003, Eazypower filed a five-count complaint against Alden, including allegations of unfair competition and patent-related violations, resulting from Alden's infringement notice letters

and soon-to-be issued patent. Specifically, the complaint contained the following claims: (1) Count I alleges a violation of section 43(a) of the Lanham Act for alleged false and/or misleading statements made to prospective customers of Eazypower; (2) Count II alleges a violation of Illinois' Uniform Deceptive Trade Practices Act; (3) Count III asserts a claim for tortious interference with prospective business relationships; (4) Count V alleges unclean hands; and (5) Count VI sought a declaratory judgment that Alden's soon-to-be-issued patent is invalid and/or not infringed by Eazypower's product. Noticeably, Eazypower did not include a Count IV in its original complaint.

***2** Alden then filed a motion to dismiss the complaint pursuant to Federal Rule 12(b)(1) and 12(b)(6) for lack of subject matter jurisdiction and failure to state a claim. Alden argues that Counts I, II, III, and V should be dismissed because its actions are immunized under the *Noerr-Pennington* doctrine. Alden also asserts that Count VI for non-infringement should be dismissed because its patent, at that time, had not issued and no actual justiciable controversy exists, and that Eazypower is simply seeking an advisory opinion.

On July 22, 2003, the day that the patent issued, Alden filed a patent infringement suit in the United States District Court for the District of Connecticut. That same day, Eazypower filed an amended complaint to include Count IV seeking declaratory judgment of non-infringement of Alden's now issued patent and amended Count IV seeking declaratory judgment of no provisional remedy. The other claims alleged in Eazypower's first complaint remain the same in the amended complaint.

Notwithstanding the filing of the amended complaint, the parties continued to brief the motion to dismiss that was filed before Eazypower amended its complaint. Although, Eazypower filed an amended complaint without leave from the Court, this Court would have granted leave. Therefore, the original complaint is moot, and we are considering this motion as a the motion to dismiss to the amended complaint.

DISCUSSION

In ruling on a motion to dismiss, the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Szumny v. Am. Gen. Fin., Inc. .,* 246 F.3d 1065, 1067 (7th Cir.2001). The purpose of a motion to dismiss is not to decide the merits of the challenged claims but to test the sufficiency of the complaint.*Weiler v. Household Fin. Corp.,* 101 F.3d 519, 524 n. 1 (7th Cir.1996). A court will grant a motion to dismiss only if it is impossible for the plaintiff to prevail under any set of facts that could be proven consistent with the allegations. *Forseth v. Village of Sussex,* 199 F.3d 363, 368 (7th Cir.2000).

I. Counts I, II, III and V of Eazypower's Amended Complaint State Claims for Relief

Alden contends that Counts I, II, III and V of Eazypower's amended complaint should be dismissed pursuant to Federal Rule 12(b)(6) for failure to state a claim on which relief could be granted. Counts I, II, III and V allege violations of the Lanham Act and Illinois Deceptive Trade Practices Act, tortious interference with prospective trade practices and unclean hands. These allegations are based on Alden's correspondence with Eazypower and its customers relating to the issuance of Alden's patent and allegations that Eazypower's Screw Remover Set would infringe the anticipated patent. Alden argues that the *Noerr-Pennington* doctrine immunizes its conduct from suit.

The *Noerr-Pennington* doctrine is based on Sherman Act considerations as well as the First Amendment right to petition the government. *Tarpley v. Keistler,* 188 F.3d 788, 794 (7th Cir.1999) ("[P]arties may petition the government for official action favorable to their interests without fear of suit, even if the result of the petition, if granted might harm the interests of others."). Originally, the

doctrine was limited to antitrust actions, but has been extended to protect acts reasonably related to the petitioning process, including the sending of cease and desist letters to alleged infringers. *See e.g.*, *Versatile Plastics v. Sknowbest, Inc.*, 247 F.Supp.2d 1098, 1103 (E.D.Wis.2003); *Thermos Co. v. Igloo Products Corp.*, 1995 WL 842002, at *4-5 (N.D.Ill. Sept.27, 1995).

***3** In *Versatile Plastics*, the plaintiffs filed an action seeking a declaratory judgment of non-infringement and also asserted claims of tortious interference, trade libel, antitrust and conspiracy resulting from infringement notice letters sent on behalf of the defendants. 247 F.Supp.2d at 1099. The court discussed the *Noerr-Pennington* doctrine and its transition from the antitrust arena into protecting acts "reasonably related to the petitioning litigation process," specifically the sending of cease and desist letters to alleged patent infringers. *Id.* at 1103-04.The court recognized that patent laws explicitly sanction and require notice letters to be sent to potential infringers in certain situations in order for the patent owner to recover damages. *Id.* at 1104.More importantly, the court acknowledged that the Federal Circuit, which has exclusive jurisdiction over patent appeals, has held that a patent owner "has the right to ... enforce its patent, and that includes threatening alleged infringers with suit."*Id.* at 1105 (quoting *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1353 (Fed.Cir.1999)). Ultimately, the court concluded that a patent holder who sends a cease and desist letter to persons believed to be infringing is entitled to some protection from liability for damages. *Id.* at 1105.

We agree. However, the protection afforded to patent owners under the *Noerr-Pennington* doctrine is not unlimited. In *Zenith Electronics Corp. v. Exzec, Inc.*, the Federal Circuit held that a patentee was not shielded from liability for unfair competition under the Lanham Act for statements made in the marketplace about potential infringement if such statements were made in bad faith. 182 F.3d 1340, 1353 (Fed.Cir.1999). Thus, *Noerr-Pennington* immunity may not extend to Alden's infringement notice letters if its correspondence with Eazypower and/or its customers was conducted in bad faith or without a reasonable belief that Eazypower's Screw Remover Set, in fact, would infringe Alden's patent.

Specifically, Eazypower has alleged that Alden's allegations of infringement were made in bad faith and without any knowledge that Eazypower's Screw Remover Set did, in fact, infringe Alden's soon-to-be-issued patent. Eazypower also argues that, although Alden stated that it would not contact any of Eazypower's customers, Alden, in fact, did correspond with some of Eazypower's customers about potential infringement. Eazypower also claims that Alden did not comply with the actual notice provisions of the relevant patent laws.

Even though Alden ultimately may be protected by the *Noerr-Pennington* doctrine, we believe that Eazypower has alleged sufficient facts of bad faith to withstand a motion to dismiss. Thus, the motion to dismiss Counts I, II, III and V is denied.

II. The Filing of the Amended Complaint Cures Count IV's Jurisdictional Defect

In Count IV of the amended complaint, Eazypower seeks a declaratory judgment of infringement and/or invalidity with respect to Alden's patent, which had not been issued at the time Eazypower filed its original complaint. Alden argues this Court lacks subject matter jurisdiction to consider this claim as there is no actual justiciable controversy as required by the Declaratory Judgment Act.

***4** Eazypower contends that the jurisdictional defect was cured by the filing of its amended complaint after Alden's patent issued. However, Alden argues that Eazypower did not seek leave from this Court to supplement its pleading as required by Federal Rule 15(d). Regardless, this Court would have granted leave to amend. Thus, the filing of the amended complaint did cure the jurisdictional de-

fect relating to Count IV, and Alden's motion to dismiss Count IV of the amended complaint is denied. Finally, the motion to dismiss does not address Count VI, which seeks a declaration of no provisional remedy under 35 U.S.C. 154(d). For this reason, Count VI withstands this motion to dismiss.

CONCLUSION

For the foregoing reasons, Alden's motion to dismiss is denied.

N.D.Ill.,2003.
Eazypower Corp. v. Alden Corp.
Not Reported in F.Supp.2d, 2003 WL 22859492 (N.D.Ill.)

END OF DOCUMENT

APPENDIX 8

C

McDonagh v. Bergan
N.D.Ill.,2003.
Only the Westlaw citation is currently available.
United States District Court,N.D. Illinois, Eastern Division.
Dr. Brian MCDONAGH, individually, and Illinois Phlebology Associates, an Illinois professional corporation, Plaintiffs,
v.
John BERGAN, Defendant.
No. 03 C 1465.

July 25, 2003.

MEMORANDUM OPINION AND ORDER

MORAN, Senior J.

***1** Plaintiffs Brian McDonagh and Illinois Phlebology Associates brought this action against defendant John Bergan alleging defamation, tortious interference with economic advantage, unfair competition and civil conspiracy arising from statements that Bergan allegedly made about a medical process developed by the plaintiffs. Defendant filed a motion to dismiss the complaint in its entirety for failure to state a claim pursuant to Fed.R.Civ.P. 12(b)(6). For the following reasons, defendant's motion is granted.

BACKGROUND

Plaintiffs are physicians who specialize in the treatment of varicose veins using a procedure known as sclerotherapy, whereby a solution is injected into the veins to sclerose them. In 1992, plaintiff Brian McDonagh developed a method of sclerotherapy now known as COMPASS, which he presented to the World Congress of Phlebology in 1995. This method, which uses ultrasound technology to guide the injections, is allegedly less invasive and less expensive than traditional surgical treatment. Defendant John Bergan is a well-known vascular surgeon who is allegedly financially involved in a surgical method of treating varicose veins which is known as VNUS Closure.

Plaintiffs allege that Bergan is frequently consulted by numerous individuals and entities, including insurance companies, regarding varicose vein treatments. They claim that Bergan, along with other unnamed parties who have a financial stake in VNUS Closure, engaged in a scheme to disparage COMPASS in an effort to advance VNUS Closure. In furtherance of this scheme defendant allegedly told various medical societies and insurance carriers that sclerotherapy was "not good medicine" and that the costs of sclerotherapy should not be covered by health insurance providers.

Plaintiffs specifically allege that defendant, in connection with insurance policy reviews, has stated:

"a. that a recent article finding COMPASS more effective than surgical alternatives, peer reviewed by surgeons and published in the leading publication in this field, the Journal "Phlebology," is baseless and false;

b. that the editors of "Phlebology" "must have been too busy" and let the referenced article through for publication "by mistake" (in fact, Bergan is himself a member of the Editorial Advisory Board of "Phlebology" and the article was reviewed for approximately nine months before publication);

c. that the COMPASS protocol could not close the sapheno-femoral junction and the greater saphenous vein and therefore was not a viable treatment alternative;

d. that the accessory branches of veins, feeders and below knee greater saphenousvein (which are treated by the COMPASS protocol but not by VNUS Closure) are "irrelevant" or should be treated by procedures not covered by insurance;

e. that the complete regeneration of the varicose or

accessory vein after surgical treatment does not constitute a failure of the treatment;

f. that an information Table (regarding the failure rate of surgical procedures) attached to the referenced COMPASS article was invalid because "most of the studies referenced" in the Table "were for high ligation and not for stripping";

***2** g. that the COMPASS treatment protocol is not an advisable or effective method to treat most varicose vein cases; and

h. that the VNUS Closure protocol for the treatment of varicose vein disease is superior to COMPASS and a more advisable protocol in most if not all cases." (Complaint, ¶ 11).[FN1]

FN1. It is unclear whether any of those representations were made within the applicable statute of limitations.

As a result of these alleged statements, plaintiffs claim that insurers have denied coverage for sclerotherapy and many patients therefore choose not to undergo the treatment.

DISCUSSION

In deciding a Rule 12(b)(6) motion to dismiss or strike a pleading we must assume the truth of all well-pleaded factual allegations, making all inferences in the non-movant's favor. *Sidney S. Arst Co. v. Pipefitters Welfare Educ. Fund,* 25 F.3d 417, 420 (7th Cir.1994). The court should dismiss a claim only if it appears "beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."*Conley v. Gibson,* 355 U.S. 41, 45-46 (1957).

Count I-Defamation

In order to state a claim for defamation, plaintiffs must allege facts showing that the defendant made a false statement of fact concerning the plaintiff, that there was an unprivileged communication of the statement to a third party, and that plaintiffs were damaged by the publication. *Myers v. The Telegraph,* 332 Ill.App.3d 917, 922, 773 N.E.2d 192, 197 (5th Dist.2002).

A statement of opinion about matters of public concern that does not contain fully provable factual elements is entirely protected by the Constitution.*Milkovich v. Lorain Journal Co.,* 497 U.S. 1, 20 (1990). This protection applies to all statements that cannot be reasonably construed as factual statements about an individual. *Id* . Under Illinois law, such a statement is not actionable if it is an opinion relating to an individual's acts rather than the individual, the listener can perceive a factual basis for the statements and draw his or her own conclusions, and the statement relates to a matter of public concern. *Lancaster Foundation v. Skolrich,* 1992 WL 211063, *3 (N.D.Ill.1992). More importantly, the Illinois courts give heightened protection to statements about medical science, a matter of public concern where widely varied approaches and opinions exist. *Aroonsakul v. Shannon,* 279 Ill.App.3d 345, 353, 664 N.E.2d 1094, 1100 (2nd Dist.1996), *citing**Spelson v. CBS, Inc.,* 581 F.Supp. 1195, 1202 (N.D.Ill.1984).[FN2]

FN2. We note that this differs from a privileged communication of a factual statement. Generally, when a physician communicates facts to an insurance carrier regarding the advisability of coverage, such a statement is protected by a qualified privilege. *See**Rodriguez-Erdmann v. Ravenswood Hospital Medical Center,* 190 Ill.App.3d 24, 32, 545 N.E.2d 979, 984 (1st Dist.1989). Such a privilege can be overcome by a showing that the defendant acted with an intent to harm the plaintiffs, as plaintiffs clearly allege here. *Id.* Expressions of opinion however are protected by the First Amendment and are never actionable, regardless of intent, because they cannot be proven true or false. *Spelson,*

581 F. Supp at 1202.

In *Aroonsakul*, defendant allegedly attacked plaintiff's treatment of numerous incurable diseases, stating that the plaintiff had no research to substantiate her claims. 279 Ill.App.3d at 348, 664 N.E.2d at 1097. She stated that the plaintiff's method was "just as outrageous as saying that toenail polish cures Parkinson's Disease, to me."*Id.* The court found that these statements were about plaintiff's treatment methods rather than defamatory statements about plaintiff individually. 279 Ill.App.3d at 353-54, 664 N.E.2d at 1100. As a result, the statements were constitutionally protected opinions. *Id.*

***3** This is not to say that all defendants are immune from suit for defamation when speaking about other physicians. Statements that impugn the character or qualifications of a physician are clearly actionable. *Barakat v. Matz*, 271 Ill.App.3d 662, 648 N.E.2d 1033 (1st Dist.1995); *Erickson v. Aetna Life & Casualty Co.*, 127 Ill.App.3d 753, 469 N.E.2d 679 (2nd Dist.1984). In *Barakat*, a doctor who was reviewing the claims of another told a workers' compensation insurer that plaintiff's "practice was a joke" and that the plaintiff was "not any good as a doctor."271 Ill.App.3d at 672, 648 N.E.2d at 1042. Because these were not expressions of disagreement over medical treatments, but rather statements about the professional conduct and character of the plaintiff, the court held that they were actionable. *Id.*

The statements allegedly made by Bergan closely resemble those in *Aroonsakul*.If plaintiffs' allegations are true, defendant criticized their method of treating varicose veins and their research in support of this method. The alleged statements are not capable of being proven true or false. Moreover, as in *Lancaster Foundation*, the statements provided third parties who heard them a factual basis with which they could draw their own conclusions about sclerotherapy and the research in support of it. 1992 WL 211063 at *3. According to Illinois law, disagreements of this type amongst medical professionals should be settled by discussion and research in the medical community, not by the courts. While courts certainly do not sanction the abuse of a position of trust by a physician, there is no actionable claim for defamation unless defendant makes *factually* misleading statements.

Plaintiffs also fail to allege that defendant's statements concerned them, as is required for a defamation claim. As stated above, the alleged statements concerned COMPASS, sclerotherapy or the research supporting plaintiffs' methods. While it is true that a defamatory statement may be actionable even if it does not mention plaintiffs by name, third parties must be able to reasonably understand that the statement refers to the plaintiffs. *Beresky v. Teschner*, 64 Ill.App.3d 848, 851, 381 N.E.2d 979, 981 (2nd Dist.1978). Defendant never actually referred to a *person* in any of the alleged statements, but rather to a *process.*Plaintiffs do not allege that the insurance carriers knew that they were involved in the development of COMPASS or that any third parties understood the statements to be about them as individuals.

Count II-Tortious Interference

To state a claim for tortious interference with economic advantage, plaintiffs must allege a reasonable expectation of a business relationship, the defendant's knowledge of that relationship, and purposeful interference in the relationship that leads to damages. *Fellhauer v. City of Geneva*, 142 Ill.2d 495, 511, 568 N.E.2d 870, 878 (Ill.1991). In addition, plaintiffs must allege that defendant has committed some impropriety while interfering. *Dowd & Dowd, Ltd. v. Gleason*, 181 Ill.2d 460, 485, 693 N.E.2d 358, 371 (Ill.1998).

***4** Plaintiffs do not sufficiently allege purposeful interference by the defendant in their business relationships. They admit that the defendant did not contact the insurance carriers, but rather the carriers asked him to serve as a consultant. In fact, in the only specific example of interference alleged in the complaint, defendant was not even involved until the appeals process, weeks after the coverage for

sclerotherapy was denied. Plaintiffs simply allege that defendant recommended to insurance carriers that they not cover costs for sclerotherapy-not enough to state a claim for tortious interference. Public policy dictates that the right of the defendant to render his opinion overcomes the plaintiff's property right in the economic advantage. *Turner v. Fletcher*, 302 Ill.App.3d 1051, 1058, 706 N.E.2d 514, 519 (4th Dist.1999).

Count III-Unfair Competition

The tort of unfair competition in Illinois has been largely codified by the Illinois Uniform Deceptive Trade Practices Act, 815 ILCS 510 *et seq.* (UDTPA). The UDTPA allows plaintiffs to seek injunctive relief, but not damages, upon a showing that they have been harmed by a competitor's business practices. 815 ILCS 510/3; *Smith v. Prime Cable of Chicago*, 276 Ill.App.3d 843, 860, 658 N.E.2d 1325, 1337 (1st Dist.1995). While the plaintiffs do not cite to the statute in their complaint, their specific allegations have been codified by the UDTPA, which states that it is a deceptive trade practice when a defendant "disparages the goods, services or business of another by false or misleading representation of fact."815 ILCS 510/2(8). While the UDTPA does not entirely preempt the common law of deceptive trade practices, plaintiff does not allege a separate common law tort that would be the basis for relief other than that provided by the UDTPA. *See**Custom Business Systems, Inc. v. Boise Cascade Corp.*, 68 Ill.App.3d 50, 52-53, 385 N.E.2d 942, 944 (2nd Dist.1979).

In any case, in order to state a claim for relief plaintiffs need to allege that defendant made false representations of fact about plaintiffs' services. As stated above, the alleged statements are defendant's medical opinions about the effectiveness of sclerotherapy and COMPASS specifically. Again, we treat statements about medical science differently from statements in other areas because of the importance of encouraging public debate for the benefit of patients. *Aroonsakul*, 279 Ill.App. at 353, 664 N.E.2d at 1100.

Medical statements are not entirely immune from characterization as false statements. Plaintiffs cite to *Mead Johnson & Co. v. Abbott Laboratories*, 201 F.3d 883 (7th Cir.2000) and *Abbott Laboratories v. Watson Pharmaceuticals, Inc.*, 2001 WL 826870 (N.D.Ill.2001), as support for their claim that statements about medical science are frequently actionable in Illinois. Both, however, are easily distinguishable. Both *Mead Johnson* and *Abbott Laboratories* involved claims for false advertising under Section 43 of the Lanham Act, 15 U.S.C. § 1125. In *Mead Johnson*, defendants claimed that their infant formula was the "1st choice of doctors," despite the fact that survey evidence did not entirely support this claim. 281 F.2d at 883-84. Likewise, in *Abbott Laboratories*, the defendant made clear misrepresentations as to the FDA approval of its competitor, claiming that because plaintiff's application with the FDA was still pending, the product was unsafe. 2001 WL 826870 at *2. In this case, no such representation was made. Further, those cases do not involve a defendant doctor opining about the efficacy of a medical procedure. While plaintiffs disagree with defendant's characterization of their process and their research, they cannot say that he was factually mistaken when giving his opinion.

Count IV-Civil Conspiracy

***5** Under Illinois law, a civil conspiracy consists of a combination of two or more persons for the purpose of accomplishing either an unlawful purpose or a lawful purpose by unlawful means. *Adcock v. Brakegate, Ltd.*, 164 Ill.2d 54, 62-63, 645 N.E.2d 888, 894 (Ill.1994). The function of the claim is to extend tort liability beyond the active wrongdoer. *Id.* In order to state a claim for civil conspiracy a plaintiff must allege both an agreement between two or more parties and an act in furtherance of the agreement. *Id.* The alleged act in furtherance must itself be tortious or unlawful in character.*Id.*

While plaintiffs allege that defendant reached agreement with multiple unnamed parties to denounce sclerotherapy, they fail to sufficiently allege any tortious acts in furtherance of the agreement. Because the agreement itself is not enough, they fail to state a claim for civil conspiracy.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss the complaint is granted.

N.D.Ill.,2003.
McDonagh v. Bergan
Not Reported in F.Supp.2d, 2003 WL 21798735 (N.D.Ill.)

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APPENDIX 9

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2006 WL 566468 (N.D.Ill.)
(Cite as: Not Reported in F.Supp.2d, 2006 WL 566468 (N.D.Ill.))

Papa John's Intern., Inc. v. Rezko
N.D.Ill.,2006.
Only the Westlaw citation is currently available.
United States District Court,N.D. Illinois, Eastern Division.
PAPA JOHN'S INTERNATIONAL, INC., a Delaware corporation, and Papa John's Food Service, Inc., a Kentucky corporation, Plaintiffs,
v.
Antoin S. REZKO, an individual resident of Illinois, et al., Defendants.
No. 04 C 3131.

March 3, 2006.

Thomas Hill Peckham, Christopher Eric Paetsch, Seyfarth Shaw, Chicago, IL, Barry T. Meek, Cassandra C. Collins, Edward T. White, Michael J. Lockerby, Hunton & Williams, Richmond, VA, for Plaintiffs.
David C. Gustman, Ami Deepak Gandhi, Kellye L. Fabian, Leland W. Hutchinson, Jr., Michael J. Kelly, Freeborn & Peters, Eugene Edward Murphy, Jr., John N. Hourihane, Jr., Murphy & Hourihane L.L.C., Mary Clare G. Bonaccorsi, Bryan Cave, Chicago, IL, for Defendants.

MEMORANDUM OPINION AND ORDER

MORAN, Senior J.
***1** Plaintiffs Papa John's International, Inc. and Papa John's Food Service, Inc. brought an action alleging trademark infringement in violation of the Trademark Act of 1946, copyright infringement in violation of the Copyright Act of 1976, trade secret misappropriation in violation of the Kentucky Uniform Trade Secrets Act, and breach of contract. The action stems from defendants' alleged non-performance and default on a series of franchise agreements and promissory notes. After defendants filed a motion to dismiss plaintiffs' second amended complaint and filed a number of counterclaims, plaintiffs filed this motion for sanctions under FED. R. CIV. P. 11 for defendants' alleged failure to make a reasonable inquiry into the fact and law underlying their filings. For the following reasons, we deny plaintiffs' motion for sanctions.

BACKGROUND

Plaintiff Papa John's International, Inc. initially brought this action against defendants PJ Chicago, LLC, Chicago P.J., LLC, and East Coast PJ, LLC on May 3, 2004. Defendants counterclaimed and plaintiffs entered two amended complaints, adding Papa John's Food Service, Inc. as a plaintiff and Antoin Rezko as a defendant. Plaintiffs allege that defendants illegally operated their restaurants under Papa John's registered trademarks, and used Papa John's registered copyrights, confidential operations manual, and other trade secrets, without paying royalties or other compensation to plaintiffs, and in violation of covenants not-to-compete. These actions allegedly took place both before and after plaintiffs were terminated as Papa John's franchisees on May 3, 2004.

On May 10, 2004, plaintiffs filed a motion for temporary restraining order or preliminary injunction. Ten days later the parties agreed to a partial resolution of that motion, wherein defendants agreed to immediate cessation of the use of plaintiffs' trademarks, confidential information regarding recipes and food products, promotional material and signs, and to display signs de-identifying their restaurants from Papa John's. On June 30, 2004, plaintiffs filed an emergency motion to show cause regarding the May 20, 2004, order. The hearing was set for August 5, 2004. Prior to the hearing, on August 4, 2004, the parties came to an agreement and entered into a written settlement agreement ("settlement agreement"). Within four months, both parties had entered motions to enforce the settlement agreement, plaintiffs filing on October 5, 2004, and defendants filing on November 23, 2004. By the middle of December 2004, settlement discussions were re-initiated. Ultimately, those settlement discussions were unsuccessful. On June 23, 2005, both parties withdrew their motions to enforce the August 4, 2004, settlement agreement-defendants' motion was withdrawn without prejudice.

On July 8, 2005, defendants filed counterclaims and moved to dismiss plaintiffs' second amended complaint, contending that "Papa John's conduct

following the signing of the Settlement Agreement prevented Defendants from fully performing their obligations under the Settlement Agreement" (defs' response, ex. 2, ¶ 7). Specifically, defendants alleged that plaintiffs were unable to come to a franchise agreement with Dr. Paul Ray, a third party to whom defendants were planning to sell their pizza stores, in large part because plaintiffs breached the terms of the settlement agreement. According to defendants, plaintiffs' "killed" the settlement agreement on May 6, 2005. Defendants' motion to dismiss plaintiffs' second amended complaint is predicated on the validity and enforceability of the settlement agreement.

***2** On October 11, 2005, with defendants' motion to dismiss outstanding, plaintiffs made this motion for sanctions. Plaintiffs argue that defendants' motion to dismiss and second counterclaim violate Rule11(b), which requires a party entering a court filing to make a reasonable inquiry into whether the allegations made therein have evidentiarysupport and are warranted by existing law or a non-frivolous argument for the alteration of the law. Plaintiffs contend that defendants' use of the settlement agreement is frivolous because it is no longer in effect, as shown through defendants' own statements. Defendants counter that the agreement is, in fact, in effect, and therefore their motion to dismiss and counterclaim are viable.

DISCUSSION

Rule 11 requires that a signatory to a court document has "read the document, has conducted a reasonable inquiry into the facts and the law and is satisfied that the document is well grounded in both, and is acting without any improper motive."*Business Guides, Inc. v. Chromatic Communications Enterprises, Inc.*, 498 U.S. 533, 542, 111 S.Ct. 922, 112 L.Ed.2d 1140 (1991). Failure to comply with such requirements will result in the imposition of sanctions, pursuant to Rule 11(c).

Rule 11 was instituted to deter baseless filings and streamline the administration of the courts. *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 393, 110 S.Ct. 2447, 110 L.Ed.2d 359 (1990). And although sanctions may include payment of the other parties' expenses, in analyzing a motion for sanctions we are mindful of the rule's ultimate goal of deterrence. *Id.* *See also**Westfield Partners, Ltd. v. Hogan*, 744 F.Supp. 189, 193 (N.D.Ill.1990) ("Compensation, although an important consideration, is not the only purpose underlying Rule 11. An even more important purpose is deterrence").

Potential violation of Rule 11 is analyzed under a negligence standard and turns on whether the conduct was objectively reasonable. *D'Aquino v. Citicorp/Diner's Club, Inc.*, 139 F.R.D. 357, 359 (N.D.Ill.1991) (*citing**Hays v. Sony Corp. of America*, 847 F.2d 412, 418 (7th Cir.1988)). Therefore, an attorney's good faith is immaterial to the imposition of sanctions. *Id.*, at 360.What constitutes a reasonable inquiry is case-specific and "may depend on such factors as how much time was available for investigation, whether counsel had to rely on a client for information as to the facts or whether the filed papers were based on a plausible view of the law."*Id.*, at 360.In this case the defendants' use of the settlement agreement as the basis for their counterclaim and motion to dismiss requires us to consider whether the papers filed were based on a plausible view of the law. If the settlement agreement was clearly void and unenforceable, as plaintiffs contend, then defendants' reliance solely on the agreement would violate Rule 11. *See**In re Alberto*, 119 B.R. 985, 992 (Bankr.N.D.Ill.1990) ("A pleading, motion, or paper is not well-grounded in fact if it is contradicted by uncontroverted evidence that was or should have been known to the attorney or the party signing the filing") (*citing**Frazier v. Cast*, 771 F.2d 259, 263-65 (7th Cir.1985)).

***3** If, however, the settlement agreement may or may not have been enforceable, defendants' actions would not violate Rule 11. Because Rule 11 only requires that an argument be grounded in fact, analysis under Rule 11 is less stringent than analysis under FED. R. CIV. P. 12(b)(6). Just because a more fully developed record would indicate that the claim or argument is erroneous does not automatically translate to violation of Rule 11.*Foster v. Michelin Tire Corp.*, 108 F.R.D. 412, 415-16 (C.D.Ill.1985).*See also**LaSalle Nat. Bank of Chicago v. County of DuPage*, 10 F.3d 1333, 1338 (7th Cir.1993) ("Because Rule 11'is not intended to chill an attorney's enthusiasm or creativity in pursuing factual or legal theories,' an attorney need not advance a winning argument to avoid Rule 11 sanctions"); *Rouhi v. Harza Engineering Co.*, 785 F.Supp. 1290,

1296 (N.D.Ill.1992) (where there is a plausible reading of the law that would support the party's filing, Rule 11 sanctions are not appropriate).

Plaintiffs contend that defendants knew the settlement agreement was null and void, and therefore their reliance on it should be subject to Rule 11 sanctions. They suggest that statements made by counsel at a December 15, 2004, status conference display defendants' knowledge that the agreement was not in effect. Plaintiffs argue that, at that conference defense counsel twice admitted that the settlement agreement was "a nullity" (plfs' motion at 7). The first statement by defense counsel, Mr. Murphy, reads: "I will have one brief comment, Judge. It is Rezko's position that the settlement agreement previously stated by counsel is not in full force and effect that if it was, in fact, breached ... as far as Rezko is concerned we do have a settlement conference in place as we stand here today" (defs' response, ex. 1, at 13:19-14:1). The second statement is plaintiffs' counsel, Mr. Lockerby, stating: "The contingency that I identified up-front is that if GE does not agree by 12:00 o'clock noon a week from today, December 22nd, 2004, then this agreement is null and void and the parties to the litigations, which do not include Dr. Ray, have an appointment with the Court on December 29th for a hearing that does not involve Dr. Ray"(*id.*, at 15:2-8). Although that statement was made by plaintiffs' counsel, it was included to show that there was no dissent to that agreement from defense counsel. Plaintiffs also suggest that the withdrawal of defendants' motion to enforce the settlement agreement, withdrawn on June 23, 2005, indicates defendants' lack of confidence in the agreement.

Defendants respond that they "and their counsel never asserted that the Settlement Agreement dated August 4, 2004 has no binding effect and is a nullity. Rather, just as Papa John's did in its motion to enforce the Settlement Agreement, Defendants consistently maintained that there was and is a binding agreement that was breached by Papa John's" (defs' response at 2). Specifically, defendants contend that Mr. Murphy's comment was "prefatory" and could not be read to state that the agreement was a nullity, which was obvious since both parties had pending motions to enforce that agreement on the date of the status conference at issue (*id.*, at 2-3). In fact, defendants did not withdraw their motion to enforce the settlement agreement for another six months. Defendants also argue that Mr. Lockerby's statement referred only to an amendment to the agreement, "the failure [of which] did not abrogate the Settlement Agreement"(*id.*, at 3). As for the withdrawal of defendants' motion to enforce the agreement, defendants note that there was no stated reason for the withdrawal, and it was withdrawn without prejudice. Therefore, the withdrawal in no way signifies that the settlement agreement was void or unenforceable.

***4** We cannot find that defendants have explicitly indicated that the August 4, 2004, settlement agreement is null and void. Reading the transcript of the status conference as a whole, defense counsel's statements did not assert that the agreement was a nullity. And the fact that the motions to enforce were still pending at the time of the statements works to support defendants' contention that neither party considered or stated that the agreement was invalid. Further, at that December 15, 2004, status conference, plaintiffs' counsel stated, "Papa John's and Rezko already signed a settlement agreement. And what we're doing now is agreeing to an amendment ..." (defs response, ex. 1, at 10:22-24). As we understood the conversation, the discussion regarded potential amendments to the settlement agreement, not the agreement as a whole. In fact, a reading of the full status conference transcript shows that the conference took place to discuss "an offer by Papa John's to amend its preexisting settlement agreement with the Rezko codefendants ..." (defs' response, ex. 1 at 4:4-8), and to aid the parties in entering into an amended binding agreement (*id.*, at 12:12-19). Therefore, the December 15, 2004, statements do not necessarily evidence that defendants considered the settlement agreement a nullity. And, standing along, the withdrawal of the motion to enforce cannot be seen as a statement that the agreement is null and void.

Defendants may still be in violation of Rule 11 if there is no reading of the law that can be applied to give them a successful claim. A settlement agreement is a contract and, therefore, is governed by the principles of local law generally applied to contracts. *D. Patrick, Inc. v. Ford Motor Co.*, 8 F.3d 455, 460 (7th Cir.1993); *Laserage Technology Corp. v. Laserage Laboratories, Inc.*, 972 F.2d 799, 802 (7th Cir.1992).[FN1] In Kentucky, a party in material breach

of a contract cannot enforce that contract. *See*Jewett v. Hertich, 2004 WL 1487105, *6 (Ky.App,Ct.2004); *Williamson v. Ingram*, 243 Ky. 749, 49 S.W.2d 1005, 1006 (Ky.App.Ct.1932). In this case both parties have asserted that the other is in breach of the settlement agreement. If it is true that defendants have breached the settlement agreement, they cannot assert the contract as the means by which to dismiss plaintiffs' second amended complaint.[FN2]We will not, however, address the merits of a breach of contract argument on this motion for sanctions under Rule 11. Although Rule 11 does impose a duty on parties and counsel to conduct reasonable inquiry into a claim or argument, "it was not intended to provide another level of pretrial review on the merits" of defendants' arguments.*Haroco, Inc. v. American Nat. Bank and Trust Co. of Chicago*, 121 F.R.D. 664, 671 (N.D.Ill.1988). Therefore, as there is clearly a debate over the enforceability of, and the adherence to the settlement agreement, we will not address the merits of such a breach in determining this motion.

> FN1. Because the franchise agreement included a choice of law provision-"this agreement and all claims arising from the relationship between us and you will be governed by the law of the Commonwealth of Kentucky without regard to its conflict of laws principles" (second am. cplt, ex. B, at 1)-we turn to Kentucky law.
>
> FN2. We note that defendants adamantly argue that they have complied with the settlement agreement to the best of their abilities, hampered only by plaintiffs' action and inaction (*see* defs' response, ex. 2, at 2).

***5** In the alternative, plaintiffs suggest that even if the settlement agreement is valid and enforceable, it cannot serve as a valid basis for a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) (plfs' reply at 5). Plaintiffs cite *Yattoni v. Oakbrook Terrace*,1991 U.S. Dist. LEXIS 10423 (N.D.Ill.1991), and the court's statement that a party cannot assert allegations outside of the complaint in a motion for dismissal pursuant to Rule 12(b)(6). It is true that in a 12(b)(6) analysis, arguments and documents attached to a defendant's pleadings cannot be considered without converting the motion to dismiss to a motion for summary judgment, with the exception of documents referred to in the plaintiff's complaint and central to the claim. *Wright v. Associated Ins. Companies Inc.*, 29 F.3d 1244, 1248 (7th Cir.1994); *Venture Associates Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir.1993). Therefore, we must inquire as to whether the settlement agreement falls into the exceptions as designated by the Seventh Circuit.

Plaintiffs do not attach the settlement agreement to the complaint, nor does the complaint make mention of it. And because the settlement agreement is essentially a release of liability, which is an affirmative defense under FED. R. CIV. P. 8(c), it appears that the agreement is not an appropriate basis for a motion to dismiss under Rule 12(b)(6).*See*United States v. Lewis, 411 F.3d 838, 842 (7th Cir.2005) (it was premature to grant a motion to dismiss based on an affirmative defense, unless the allegations of the complaint set forth everything necessary to satisfy the affirmative defense); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir.2004). Other courts, however, have found that the presence of a settlement agreement or liability release is appropriately considered on a motion to dismiss, even where the plaintiff did not attach it to his complaint. *See*Stiegmeier v. Northwestern Growth Corp., 2000 WL 1670931, *2 (S.D.N.Y.2000) (considered a settlement agreement on a motion to dismiss where a related document was referred to in the complaint, the parties had notice of both documents, and the documents were integral to his claims); *Willis Corroon Corp. of Utah, Inc. v. United Capitol Ins. Co.*, 1998 WL 30069, *3 (N.D.Cal.1998) ("while the interim settlement agreement may not be 'central' to the substantive issues in Corroon's complaint, it clearly is central to Corroon's ability to bring this action since the agreement is a binding contract which allegedly limits the parties' right to sue. The agreement is therefore centrally relevant-and potentially dispositive-in the same way that facts indicating the existence of a statute of limitations or res judicata would be").*See also*Ficke v. Johns, 1996 WL 99424 (N.D.Ill.1996) (in addition to a reference to the release in the complaint, the release was "clearly central to plaintiff's allegations in that a determination of the Release's validity affects whether or not this action may proceed").

***6** As indicated above, there are conflicting views as to whether a settlement agreement-central to the claim's viability, but now here mentioned in the

complaint-should be considered on a motion to dismiss. Therefore, we find that the use of such a document is not so clearly objectionable as to require the imposition of sanctions.

CONCLUSION

For the foregoing reasons, we deny plaintiffs' motion for sanction under Rule 11.

N.D.Ill.,2006.
Papa John's Intern., Inc. v. Rezko
Not Reported in F.Supp.2d, 2006 WL 566468 (N.D.Ill.)

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